

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

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In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC  
Products Liability Litigation )  
 ) Phoenix, Arizona  
 ) May 16, 2018  
 )  
Doris Jones, an individual, )  
 )  
Plaintiff, )  
 ) CV-16-00782-PHX-DGC  
v. )  
 )  
C.R. Bard, Inc., a New Jersey )  
corporation; and Bard Peripheral )  
Vascular, Inc., an Arizona )  
corporation, )  
 )  
Defendants. )

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BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 2 - A.M. SESSION

(Pages 231 - 344)

Official Court Reporter:  
Patricia Lyons, RMR, CRR  
Sandra Day O'Connor U.S. Courthouse, Ste. 312  
401 West Washington Street, SPC 41  
Phoenix, Arizona 85003-2150  
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter  
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**A P P E A R A N C E S**

For Plaintiff:

Gallagher & Kennedy  
By: **MARK S. O'CONNOR**, ESQ.  
By: **PAUL L. STOLLER**, ESQ.  
By: **SHANNON L. CLARK**, ESQ.  
By: **C. LINCOLN COMBS**, ESQ.  
2575 East Camelback Road, Suite 1100  
Phoenix, AZ 85016

Lopez McHugh, LLP  
By: **JOSHUA MANKOFF**, ESQ.  
214 Flynn Ave.  
Moorestown, NJ 08057

Heaviside Reed Zaic  
By: **JULIA REED ZAIC**, ESQ.  
By: **LAURA E. SMITH**, ESQ.  
312 Broadway, Ste. 203  
Laguna Beach, CA 92651

For Defendants:

Nelson Mullins Riley & Scarborough  
By: **RICHARD B. NORTH, JR.** ESQ.  
By: **ELIZABETH C. HELM**, ESQ.  
201 17th Street NW, Suite 1700  
Atlanta, GA 30363

Nelson Mullins Riley & Scarborough.  
BY: **JAMES F. ROGERS**, ESQ.  
1320 Main St.  
Columbia, SC 29201

Snell & Wilmer  
By: **AMANDA C. SHERIDAN**, ESQ.  
400 East Van Buren  
Phoenix, AZ 85004

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P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Counsel, do you have matters we need to address this morning before we get started?

MR. O'CONNOR: Possibly with Dr. Asch.

MR. CLARK: I have a very short one, Your Honor.

We have a number of exhibits that we have, I think, agreed can come into evidence and I would like to move those into evidence now.

THE COURT: Let's do it in front of the jury.

MR. CLARK: Is that better?

THE COURT: Well, they need to know they're in evidence.

MR. CLARK: Fair enough.

THE COURT: If there are issues we need to discuss, I'm happy to do that, but I'd like you to move them into evidence in front of the jury so they know they're in evidence.

MR. CLARK: One other thing related to that. Since most of these relate to deposition exhibits that are now trial

08:31:18 1 exhibits, would it be okay to prepare sort of a chart that we  
2 can give to the jury, and perhaps the first time the Court can  
3 instruct them for their convenience we've done the conversion  
4 from trial exhibit to deposition exhibit? I noticed they were  
08:31:31 5 taking notes when we were talking about that yesterday, and it  
6 seems that process is a little cumbersome, so I would like --

7 THE COURT: So this would just list trial exhibit  
8 numbers and the corresponding deposition exhibit numbers?

9 MR. CLARK: For each witness; correct.

08:31:43 10 THE COURT: Any objection?

11 MR. NORTH: No objection, Your Honor.

12 THE COURT: Yeah, I actually think that would be  
13 helpful because even I was having trouble keeping up with  
14 which exhibits were which.

08:31:52 15 MR. CLARK: That will make me not read as fast too.  
16 Thank you.

17 THE COURT: Anything else we need to address?

18 MR. NORTH: Nothing for the defendants, Your Honor.

19 Oh, I'm sorry, there is one document.

08:32:03 20 MR. O'CONNOR: Just the issue, Your Honor, Dr. Asch  
21 is going to testify. There's an Exhibit 5247. We've got the  
22 exhibits the defense intends to use with Dr. Asch. Setting  
23 aside the hearsay nature, they have redacted, I think, in  
24 accordance with your order, but the redactions, again, they  
08:32:34 25 deal with presumably death, but I know we raised the issue

08:32:39 1 yesterday and I know that the issue is being taken under  
2 advisement, but over -- for example, the statement in this  
3 Dear Colleague letter says overall migration-related fatality  
4 rate is below the reported 0.1 percent. They want to redact  
08:33:01 5 "fatality."

6 Again, this is just the same problem with this order.  
7 I don't think the jury's going to understand, if this document  
8 even gets in, what rate they're talking about that is less  
9 than 1 percent.

08:33:12 10 THE COURT: Is this a document that you understand  
11 defendants are going to use in the examination of Dr. Asch?

12 MR. O'CONNOR: Yes. We had exchanged them last  
13 night. They were kind enough to show me what they're going to  
14 redact. I had told them back that I was going to raise this  
08:33:26 15 issue with you in view of what we talked about yesterday and,  
16 really, whether this document really completely falls within  
17 your order. Admittedly, it does talk about migration-related  
18 fatalities, and it's a Dear Colleague letter. They want to  
19 show it to Dr. Asch.

08:33:46 20 MS. HELM: Your Honor, I have a copy of the document,  
21 if that would help you.

22 THE COURT: Yes, that would help.

23 MS. HELM: I'm happy to hand you a copy with proposed  
24 redactions. That would probably be the most --

08:34:04 25 THE COURT: Okay.

08:34:10 1 So is it the highlighted material you propose to  
2 redact?

3 MS. HELM: Yes, Your Honor. Only the first page.

4 THE COURT: How are you going to use this document,  
08:34:17 5 Ms. Helm?

6 MS. HELM: Actually, Mr. North is not a hundred  
7 percent sure he's going to use it, but it's a possibility  
8 he'll use it with Dr. Asch on cross, and so we listed it on  
9 our exhibit list.

08:34:27 10 THE COURT: So at some point you'll move it into  
11 evidence?

12 MS. HELM: Possibly, yes.

13 THE COURT: Okay. Let me just look at these  
14 redactions.

08:34:41 15 Is this a letter sent to doctors?

16 MS. HELM: Yes, Your Honor. By Bard. Relating to  
17 the Recovery filter.

18 THE COURT: Help me understand, Ms. Helm, what it is  
19 you believe the relevancy of this document to be. Or  
08:36:23 20 Mr. North. That's fine.

21 MR. NORTH: Again, I'm not certain I will use that,  
22 but Dr. Asch in the past, who conducted the clinical study on  
23 Recovery, has taken the position and testified repeatedly that  
24 Bard failed to warn him when adverse events were occurring in  
08:36:36 25 the field. This was a Dear Doctor colleague letter that was



08:36:40 1 sent out to doctors, and we have evidence that it was sent to  
2 him.

3 If we decide to use it, it would be to rebut the --  
4 his contention that he was never notified and that somehow  
08:36:51 5 Bard was hiding the occurrence of adverse events from him.

6 THE COURT: And the basis for the redactions is what?

7 MR. NORTH: The reference to migration-related  
8 deaths.

9 THE COURT: And you understand these to be Recovery  
08:37:09 10 filter cephalad migration deaths?

11 MR. NORTH: Yes.

12 THE COURT: Okay.

13 Mr. O'Connor?

14 MR. O'CONNOR: I think the problem is broader than  
08:37:18 15 that, Your Honor. And I'm just going by what happened here  
16 last time in trial.

17 So Dr. Asch is going to testify that there was a  
18 cephalad migration in his study, and that it concerned him.  
19 And it concerned him that it could be potentially fatal. I  
08:37:31 20 think that is fair game under your order.

21 His testimony's going to be that he had been told by  
22 Bard there was going to be a long-term study, that he had  
23 advised Bard that they needed to look at these filters more in  
24 view of the complications he saw.

08:37:49 25 The defense, on cross-examination, are going to ask

08:37:52 1 him if he continued to use Recovery filters, and he's going to  
2 say yes, he did, and he's going to explain why.

3 But at some point he stopped. And he stopped because  
4 he learned on the streets, not from Bard, but because of the  
08:38:07 5 reports that were coming in about the complications, including  
6 the fatal complications.

7 So they're going to go into that, and they want to  
8 only tell half the story. And that's what's going to happen  
9 with a number of these doctors. And especially with Dr. Asch  
08:38:22 10 here.

11 A reason -- and it's necessary to put all of this  
12 testimony in context that he finally stopped using these  
13 filters is because he realized it was not a long-term study.  
14 And not only that, through sources other than Bard, he heard  
08:38:37 15 and found out what the medical community was finding out, that  
16 these things were killing people.

17 So at every corner, they can open the door to this.

18 THE COURT: Well, the argument -- I think the  
19 argument you just made, Mr. O'Connor, is a bit different from  
08:38:51 20 where we started, which is with this exhibit. You're now  
21 arguing, I think, that you should be able to elicit cephalad  
22 migration evidence as part of Dr. Asch's testimony regardless  
23 of whether this exhibit issues.

24 MR. O'CONNOR: I agree. I think they're somewhat  
08:39:10 25 interrelated because they want to use this to show Dr. Asch

08:39:13 1 that there were warnings, that he felt he wasn't warned. This  
2 document was faxed to him. But along those lines, his  
3 testimony would be, and, yes, I stopped using filters not  
4 because of necessarily a warning you gave me, because I was  
08:39:28 5 finding out about deaths on my own.

6 So I think that these are interrelated. How they  
7 want to use them and the doors that are going to open, and the  
8 problem is this jury's never going to hear the complete sense  
9 of the complete picture of his testimony explaining why he did  
08:39:46 10 things.

11 THE COURT: Mr. North?

12 MR. NORTH: Your Honor, I would respectfully submit  
13 that this is somewhat of a hypothetical debate right now,  
14 because a lot will depend on what Dr. Asch says, what  
08:39:56 15 questions are asked him, both on direct and cross.

16 Again, I'm not even certain I'm going to use this  
17 document as an exhibit. If I did, I don't believe that I  
18 would need to publish it to the jury. We certainly can talk  
19 about redactions afterwards if we decide to use it.

08:40:17 20 The fact of the matter is, though, I believe they're  
21 trying to use Dr. Asch as a way to further seek  
22 reconsideration of the Court's order. Dr. Asch has previously  
23 testified that he was concerned about the Recovery filter and  
24 did not believe it was ready to go to market, based on his  
08:40:34 25 personal experience in his study, clinical study, where there

08:40:39 1 was one asymptomatic migration and one asymptomatic fracture.  
2 And he said Bard had promised him they would do a European  
3 study before they put this thing on the market. Yet he  
4 continued to use the device in his practice.

08:40:54 5 That's why we're trying to get in the fact that he  
6 continued to use the Recovery filter, to refute his testimony  
7 and claim that we exploited and misused his clinical study to  
8 bring the device to market when it wasn't ready to do so.

9 THE COURT: Well, I assume you all saw the order I  
08:41:19 10 entered last night. I'm continuing to be of the view that  
11 cephalad migration deaths from Recovery filters are  
12 inadmissible under Rule 403. I continue to think the  
13 relevancy to this Eclipse case is marginal enough that the  
14 danger of unfair prejudice outweighs that relevancy. I know  
08:41:38 15 the plaintiff disagrees with that. But that's my conclusion  
16 after looking at it four times now, I think, including last  
17 night again.

18 However, as you also saw in that order, I do think  
19 it's going to be fair, when we get to the point of the  
08:41:53 20 defendant presenting evidence about the number of deaths and  
21 statistics you can conclude from that, for the plaintiff to go  
22 into the true number of deaths, and we'll decide the scope of  
23 it then.

24 I think I'm going to have to do the same thing at  
08:42:05 25 other points in the trial. If I conclude during the testimony

08:42:08 1 of Dr. Asch that there is some fairness point that needs to be  
2 addressed for his testimony to be accurate, I'll be happy to  
3 consider it at that point. But I'm not going to -- I can't  
4 conclude this morning that the door's been opened and we can  
08:42:22 5 go into cephalad migration deaths. I'm still of the view  
6 that's barred by Rule 403.

7 So I think what we ought to do is go forward with  
8 Mr. Asch -- Dr. Asch's testimony. At this point my ruling  
9 stands. So the cephalad migration references in this exhibit  
08:42:38 10 should be redacted. But if plaintiff's counsel thinks, during  
11 his testimony or afterward, that a door has been opened that  
12 in fairness ought to allow you to do something, I'd be happy  
13 to hear it at that point, because I want to make sure you  
14 don't have an unfair case to present. But I'm still convinced  
08:42:57 15 that that's a Rule 403 ruling that's correct.

16 So what I'm saying is I'm not going to rule in your  
17 favor now, Mr. O'Connor. If you want to raise the issue at  
18 sidebar before redirect after Bard has cross-examined, I'll be  
19 happy to consider what you have to say at that point.

08:43:15 20 MR. O'CONNOR: All right. Well, just so we're all --  
21 and I know your order, Your Honor, and you had told us that  
22 nothing precludes us to talk about the risks of death, and he  
23 is going to talk about that. That was his concern.

24 My problem now is how do I present him? Because  
08:43:33 25 putting this witness on, do I want to have him explain up

08:43:39 1 front, when I know what the cross-examination's going to be,  
2 or do I approach the bench with you, because the problem's  
3 going to be that only part of the story's going to be told,  
4 that he continued to use the Recovery. And he will say he  
08:43:52 5 stopped. But this jury's never going to understand why he  
6 stopped. And he stopped because --

7 THE COURT: Well, here's my problem with that  
8 argument, Mr. O'Connor, so you understand my thinking. Your  
9 primary point through Dr. Asch is going to be that on the  
08:44:07 10 basis of his studies, he had serious concerns about the  
11 Recovery filter and he expressed them to Bard, and Bard told  
12 him there would be a larger study, and the larger study never  
13 happened. That, to me, is the main point you want to get  
14 across.

08:44:22 15 Now, Bard is going to impeach him in part by saying,  
16 well, with all these concerns, Doctor, you kept using the  
17 filter. And that is to undercut his credibility he thought  
18 there was a serious problem.

19 It seems to me your rebuttal to that is he stopped  
08:44:37 20 doing that. He stopped doing it because he became concerned  
21 about the -- more concerned about the safety of the Recovery,  
22 and so he stopped.

23 That responds to their rebuttal.

24 Now, the reason he stopped, whether it's he had  
08:44:50 25 continuing concerns or specifically he heard about cephalad

08:44:54 1 migration deaths, again, to me, isn't as important as the  
2 point that he stopped because he had continuing concerns,  
3 which responds to their point.

4 So I'm not seeing your unfair advantage at this  
08:45:07 5 point. But if you believe, after you've done your direct and  
6 they've crossed on this issue, that the only fair way to  
7 respond fully to their attempted impeachment is to bring out  
8 the evidence of the deaths, I'll be happy to hear you at that  
9 point. But right now I can't conclude that that's going to be  
08:45:25 10 a necessary fairness point.

11 MR. O'CONNOR: If I can just make one point just so  
12 my record's clear. I understand what you're saying and I  
13 understand your reasoning, Your Honor. But their argument,  
14 every minute they get, is all filters fail and that the  
08:45:37 15 Recovery was failing, Dr. Asch knew it, and he continued to  
16 use it. He stopped.

17 The jury's going to wonder, well, that's kind of  
18 self-serving for him to put his testimony -- I just want this  
19 to be clear on the record -- why he stopped. It's because he  
08:45:52 20 learned about something much more serious than Bard was  
21 leading people to believe. Much more serious than what's  
22 happening in this trial. And that's what caused him and many  
23 doctors to stop.

24 So I just want the record to be clear that's why I  
08:46:08 25 think it's important, so the jury can hear this witness and

08:46:11 1 evaluate his credibility completely, not with half-truths and  
2 not with half stories.

3 THE COURT: I understand your point.

4 MR. O'CONNOR: Thank you.

08:46:20 5 THE COURT: All right. Any other matters we need to  
6 raise?

7 MS. HELM: No, Your Honor.

8 May I get that exhibit back so we can redact it.

9 THE COURT: Yes.

08:46:27 10 Mr. Combs.

11 MR. COMBS: Your Honor, just a preview. We filed a  
12 bench brief last night, somewhat of a response to Bard's bench  
13 brief a night or two before. Unless you're keeping the same  
14 hours that we are, I doubt you read it, but I think it's  
08:46:44 15 something we need to raise tomorrow morning before --

16 THE COURT: This is on the Childs issue?

17 MR. COMBS: Yes. But when Mr. Modra testifies, we  
18 want to have that clarified.

19 THE COURT: I haven't read your brief. We've  
08:46:56 20 reviewed the government's brief. We're looking at the cases  
21 you cite that you think counteract the effect of the Childs  
22 case. I'll look at what you have filed.

23 So when do you think this is coming up?

24 MR. COMBS: I think it's coming up just tomorrow  
08:47:12 25 morning, before we call Mr. Modra.



08:47:14 1 THE COURT: You're calling Modra tomorrow?

2 MR. COMBS: I think that's correct, yes.

3 THE COURT: So you're hoping to get in those reports,

4 the MDR, is that what they're called, reports?

08:47:24 5 MR. COMBS: Monthly management reports. And then

6 also a 1006 summary of all of the complaints historically.

7 THE COURT: Okay.

8 All right. We will -- I will look at your brief,

9 we'll continue looking at the cases that have been cited.

08:47:40 10 MR. COMBS: Thank you, Your Honor.

11 MS. REED ZAIC: Housekeeping note, Your Honor. You

12 said you reviewed the government's brief. It's actually

13 Bard's brief. I'm not trying to call it a misspeak. I just

14 wanted to make a record that the government hasn't entered a

08:47:53 15 brief.

16 THE COURT: Thanks.

17 All right. We'll bring the jury in at 9:00.

18 MR. COMBS: I think we all understand we're used to

19 the government siting over there.

08:48:03 20 THE COURT: Actually, they actually sit there.

21 Thanks for trying to help me out.

22 MR. COMBS: That's right.

23 THE COURT: The burden of proof.

24 MR. COMBS: That's right.

08:48:14 25 MR. O'CONNOR: Your Honor, mind if I step out?

08:48:16 1 THE COURT: Yeah.

2 (Recess was taken from 8:48 to 9:00. Proceedings resumed

3 in open court with the jury present.)

4 THE COURT: Thank you. Please be seated.

09:01:48 5 Good morning, ladies and gentlemen. Thanks for being

6 with us this morning.

7 Counsel, I wanted to mention something. Juror 6

8 mentioned to Traci that he has a bit of color-blindness and

9 has difficulty distinguishing red.

09:02:04 10 Is that right?

11 JUROR: Yes. Red text versus black.

12 THE COURT: Red text versus black.

13 So in illustrations or charts or things like that, if

14 you want to emphasize something, don't do it in red because

09:02:18 15 Juror 6 won't see the emphasis.

16 We will continue the testimony this morning with the

17 deposition testimony we left off yesterday.

18 (Video testimony of Gin Schulz played.)

19 MR. O'CONNOR: Your Honor, I think that concludes the

09:24:20 20 video.

21 At this time we call Dr. Murray Asch.

22 THE COURT: All right.

23 THE COURTROOM DEPUTY: Dr. Asch, if you'll please

24 come forward. You can stand right here and raise your right

09:24:56 25 hand, sir.

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

**DR. MURRAY ASCH,**

called as a witness herein, after having been first duly sworn  
or affirmed, was examined and testified as follows:

MR. O'CONNOR: May I proceed?

THE COURT: Yes.

D I R E C T E X A M I N A T I O N

BY MR. O'CONNOR:

Q Good morning. Would you tell the members of the jury your  
name, please.

A My name is Murray Asch.

Q You're a medical doctor?

A Yes, I am.

Q Dr. Asch, where are you from?

A I'm from Oshawa, Ontario, Canada.

Q And what do you do in Canada? What type of medicine do  
you practice?

A I'm an interventional radiologist.

Q Would you explain to the members of the jury what an  
interventional radiologist is.

A Well, it should be fairly simple. I'm sure all of you

have heard the recent discussion about Mrs. Trump and the

procedure she underwent, an embolization of a kidney. So

that's a procedure performed by interventional radiologists.

We do procedures using ultrasound and CT and X-ray, and using

tools like needles and tubes and specialized devices, we do

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

09:26:27 1 biopsies, we drain organs, we block blood vessels, and  
2 replace IVC filters and remove IVC filters.

3 Q Is an interventional radiologist different than a  
4 radiologist who, say, reads radiographic studies, a clinical  
09:26:47 5 or diagnostic radiologist?

6 A Yes. So interventional radiologists have specialized and  
7 additional training where we spend time working surgical-like  
8 suites where we do these kind of procedures. General  
9 radiologists read CATs and have specialized training as well.

09:27:01 10 They read CAT scans, do ultrasounds, and read MRIs, but they  
11 don't typically do procedures.

12 Q Now, you have -- have you set forth your education and  
13 professional credentials in what is known as a curriculum  
14 vitae?

09:27:18 15 A Yes.

16 MR. O'CONNOR: May I display Exhibit 4555.001?

17 THE COURT: To the witness?

18 MR. O'CONNOR: To the witness, yes.

19 BY MR. O'CONNOR:

09:27:35 20 Q Would you describe what you are looking at, Dr. Asch?

21 A So that is my curriculum vitae, my resume. Summary of  
22 all my education and experience.

23 Q Dr. Asch, would you tell us your education, what training  
24 you received to become a interventional radiologist?

09:27:55 25 A I'll start with medical school instead of going back

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

09:27:58 1 further than that.

2 Q Thank you.

3 A So I went to medical school, four years of medical  
4 school. I then did two years of additional generalized  
09:28:07 5 internal medicine training. Following that I did four years  
6 of a diagnostic radiology residency training program. And  
7 following that I did one year of specialized subspecialty  
8 fellowship in interventional radiology.

9 Q And where -- what institutions did you receive that  
09:28:27 10 training at?

11 A I went to medical school in London Ontario, University of  
12 Western Ontario. I did my internship in Hamilton, Ontario.  
13 And all of my radiology residency and fellowship was done at  
14 University of Toronto in Toronto.

09:28:44 15 Q And when you talk about residency and fellowship, can you  
16 explain what that means and where that places you as a medical  
17 doctor?

18 A So residency is the basic training that people will get  
19 residencies in different specialties to be a radiologist, to  
09:29:03 20 become a surgeon, to become an internist, to become a  
21 dermatologist. So that is a generalized training that is the  
22 minimum requirement to go out and practice. Many people,  
23 myself included, would want additional training, subspecialty  
24 training, in order to become a super specialist, if you will.  
09:29:22 25 So that additional year of subspecialty training was called a

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

09:29:26 1 fellowship. So that's the year where, after becoming a  
2 diagnostic radiologist, I spent an entire year essentially  
3 doing interventional radiology procedures under the guidance  
4 of a variety of trained experts.

09:29:39 5 Q In the time period of 1999, 2000, where were you working  
6 at that time?

7 A I worked in Toronto at what was then called Mount Sinai  
8 Hospital.

9 Q Were you involved in academics at all?

09:29:55 10 A Yes. Mount Sinai is one of the University of Toronto  
11 academic teaching hospitals, so I had a variety of roles in  
12 addition to clinical work, doing treating patients, helping  
13 patients. I taught medical students, and I did a variety of  
14 forms of research.

09:30:12 15 Q In your practice, have you been published?

16 A Yes, I have. Many publications.

17 Q Have you been published in anything that has to deal with  
18 IVC, inferior vena cava filters?

19 A Yes. There are a number of publications I have with  
09:30:30 20 respect to a variety of types of permanent and temporary IVC  
21 filters.

22 Q And can you just explain for us what it means when a  
23 doctor publishes an article? Why would a doctor undertake  
24 that and how is that literature generally used in the medical  
09:30:50 25 community?

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

09:31:00 1 A We do research to try to promote and progress and enhance  
2 the knowledge throughout the medical community, to share our  
3 experience in a scientific way in order to guide other  
4 physicians to change their practice. Things in -- in  
09:31:14 5 particular, interventional radiology really are constantly  
6 evolving, and the majority of procedures I do now weren't  
7 invented, if you will, when I trained. So we learn  
8 procedures based on reading articles, based on sharing  
9 information through societies and at meetings with other  
09:31:32 10 physicians. So I, like others, have chosen to write  
11 scientific published manuscript papers in order to share my  
12 experience, in order to improve patient care throughout the  
13 world.

14 Q Thank you.

09:31:47 15 Do you consult -- you treat patients as a medical  
16 doctor?

17 A Yes, I do.

18 Q Do you consult with medical device companies?

19 A Yes. I'm a consultant -- I have done and I continue to  
09:32:01 20 be a consultant for a variety of medical device companies.

21 Q And do you -- when you do medical consulting, do you  
22 charge for your time?

23 A Yes, I do.

24 Q Currently, where do you practice?

09:32:16 25 A Currently, I practice at a large community academics

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center in Oshawa, Ontario.

Q And would you just tell us, are you with a group of interventional radiologists? Or give us an idea of the people you work with.

A So we have a group currently of approximately 13 radiologists, interventional radiologists and general radiologists, and we all pool our work and pool our resources and pool our income, so we all work together and share patients and share the workload.

Q Why are you here today? Do you understand?

A I'm here today because I feel responsible for the widespread use of what was initially called the Recovery filter, and I'm concerned about it and concerned about the damage it's caused some patients. And I'm here to ensure that I can do everything I can to try and make that better.

Q Now, you, back in the 1999, 2000 time period -- first of all, you are involved in professional societies and associations; correct?

A Yes, I am.

Q And what is SIR?

A SIR is the largest interventional society in the world. It stands for Society of Interventional Radiology. The head office is in the States. And I am a fellow and used to be on the board of -- and continue to be a member/fellow of the SIR.



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09:33:50 1 Q Now, Dr. Asch, were you involved in a pilot study for  
2 Bard?

3 A Yes, I was.

4 Q And when was that?

09:33:57 5 A The initial discussions began in 1999.

6 Q And tell us a brief overview of what the intent behind  
7 that pilot study was.

8 A Well, pilot study is a great word. And the initial  
9 intent was to try and assess a brand-new never been used  
09:34:15 10 filter in a human to see if it could be safely retrieved.

11 Q Were you retained at that time as a consultant?

12 A Yes, I was.

13 Q And were you paid?

14 A Yes, I was.

09:34:26 15 Q By Bard?

16 A Yes.

17 Q Now, you've come down here all the way from Canada. Have  
18 you been compensated for your time?

19 A Yes, I have.

09:34:39 20 Q Can you explain to the jury how your compensation was paid  
21 to you by this side, the plaintiff's side, to get you here.

22 A Well, the compensation for being here today is identical  
23 to the compensation I receive for any other medicolegal work  
24 I do and all of the other work I did for Bard and for all  
09:34:57 25 other medical device companies that I currently work with,

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09:35:00 1 and that's essentially to replace the income that I am  
2 missing because I'm here. Because I work in a group  
3 practice, I can't just cancel my patients and not show up to  
4 work. I'm losing income and at the same time I need to make  
09:35:14 5 someone available to do the work that I am not doing. So I'm  
6 being compensated for that.

7 Q And so for consulting medicolegal, what are you charging?

8 A Depending how many hours it involves or if it's during  
9 work or after work, it's either an hourly rate or a daily  
09:35:33 10 rate. Typically it is around \$700 per hour.

11 Q And then if you're going to be gone for -- how many  
12 days -- to get here, how many days did this take you away from  
13 your practice?

14 A Four days.

09:35:46 15 Q And how do you obtain compensation for that?

16 A So the -- I earn approximately -- I earn a good living.  
17 I earn approximately \$5,000 a day, so I've been paid to  
18 replace my income.

19 Q Dr. Asch, were your travel expenses paid for?

09:36:05 20 A Yes, they were.

21 Q Now, Dr. Asch, let's go back to 1999 or that period, and  
22 if you can explain to the jury the circumstances, how you were  
23 approached that got you the start of your involvement in the  
24 Bard pilot study.

09:36:26 25 A This all started at one of the SIR annual meetings. I

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09:36:30 1 was attending a meeting, and a group of individuals from Bard  
2 and, at that time, NMT approached me and said, we've got a  
3 novel idea for a new, never been used filter, and we would  
4 like you to be involved in the first human use pilot project  
09:36:46 5 to assess the retrievability of this. And that was the  
6 initial hallway discussion.

7 Following that, we sat down and met. And then I was  
8 flown to Boston where, at that time, NMT head office was, and  
9 I met with a group of individuals from Bard and NMT, and they  
09:37:08 10 gave me background information about the device and the  
11 planned project so that we could work together and move  
12 forward as a team.

13 Q Was there a presentation made to you?

14 A Yes. So they gave me a presentation to give me a  
09:37:23 15 background on how the filter was designed. I hadn't been  
16 involved in filter design. They came to me with a filter  
17 that was designed and had been in preclinical testing, bench  
18 top testing, and animal testing, so they showed me all of the  
19 data that they had to satisfy my concerns about being the  
09:37:41 20 first person to place a device in a human. Obviously, that's  
21 a scary thing. I feel responsible for that.

22 And after answering all those questions, we then  
23 moved forward with a proposal I could bring to my hospital, my  
24 ethics board, my government in order to obtain permission to  
09:38:01 25 use the device.

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09:38:02 1 Q Now, when you say your government, that's in Canada?

2 A Yeah. In Canada, we have something called the Health  
3 Protection Branch, which oversees use of medications and  
4 medical devices.

09:38:13 5 Q Did people from Bard explain to you why they wanted to do  
6 this pilot study in Canada?

7 A Yes. The feeling I had from them was that because of  
8 political differences in the different countries, it would be  
9 easier to do a study like this in Canada than it would in the  
09:38:29 10 United States.

11 Q Different regulatory pathway in Canada?

12 A Yeah. So the Canadian government is felt at times to be  
13 more lenient. Again, coming with a brand-new filter never  
14 been used in a human before, there's lots of potential  
09:38:44 15 concern about this, and it was felt that the Canadian  
16 government would be more open and welcome to that.

17 Q So the purpose of the study, as you understood it, was to  
18 look at the retrievability of a Bard filter?

19 A Yes. That was the single task that I was given, pilot  
09:39:02 20 project, assess safety of removal of the device.

21 Q Was your study to be used at all for any type of long-term  
22 clinical study for safety or efficacy?

23 A No. The understanding that I had was this was a -- pilot  
24 study is a great word. A pilot study to obtain initial human  
09:39:21 25 safety information, and then that information will be taken

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back to the United States in order to pave the way for performing a long-term multicenter larger study to assess other aspects of the filter, including long-term safety.

Q Was it your understanding that Bard -- did Bard indicate to you that the company intended to a long-term safety study after your study?

A Yes. In all of our discussions, that was a repeated theme, long-term safety study after my pilot study.

Q So to do this study, how did your -- what was your involvement in the beginning? Did you design the study? Were you involved in that?

A I did not design the study or the filter, no. So Bard and NMT worked together and provided me with all of the documentation that I needed to supply to my ethics department and to the government. So they gave me the introductory package that I had already been shown at NMT, they gave me a consent form, and they gave me a study protocol, all of which I then submitted to the regulatory bodies.

MR. O'CONNOR: Gay, can you put up and display to the witness Exhibit 556.

And can you scroll through each page.

BY MR. O'CONNOR:

Q And, Dr. Asch, if you could review it and tell us if you recognize these documents.

A Yes. This is the package I just described. So that's

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1 what -- you can't see it. What is up there right now is the  
2 study design and the letter, copies of letters that I had  
3 written to the ethics department and Health Canada asking for  
4 permission to use the device for this pilot study.

5 Q Are these documents that you received from Bard and  
6 related entities to initiate your study?

7 A Yes.

8 MR. O'CONNOR: Move for admission of Exhibit 556.

9 MR. NORTH: No objection, Your Honor.

10 THE COURT: 556 is admitted.

11 (Exhibit 556 admitted.)

12 MR. O'CONNOR: Thank you.

13 Let's go to --

14 Oh. May we publish to the jury, Your Honor?

15 THE COURT: You may.

16 MR. O'CONNOR: Thank you.

17 Gay, let's go to the third page, please.

18 BY MR. O'CONNOR:

19 Q Dr. Asch, can you explain to us what we're looking at  
20 here?

21 A So this is a letter of approval from the chair of the  
22 Mount Sinai Hospital research ethics board indicating  
23 approval, indicating permission for me to use the device.  
24 The typical permission, as indicated here, allows for 12  
25 months and a limited number of devices, in this case 20, at

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09:42:58 1 which time I need to reapply for permission.

2 Q And did that eventually happen?

3 A Yes.

4 MR. O'CONNOR: Go to the next page, Gay.

09:43:07 5 BY MR. O'CONNOR:

6 Q We're looking at another letter dated November 8, 2001.

7 Could you tell us what this letter is, please.

8 A That is a letter from the chair of the research ethics  
9 board of the hospital allowing me to proceed with the study  
09:43:29 10 as requested.

11 MR. O'CONNOR: And then the next page, Gay.

12 THE WITNESS: So that is page 1 of the study  
13 proposal.

14 BY MR. O'CONNOR:

09:43:45 15 Q And is this what was an outline of how the study would  
16 proceed?

17 A Yes.

18 Q And who provided this to you?

19 A That was provided to me by the team, referred to as the  
09:44:04 20 team, the team from NMT and Bard.

21 Q If you look down below, can you explain to the jury how  
22 the study was going to begin with patients and inserting  
23 filters in these patients.

24 A We were going to take patients that had the standard  
09:44:30 25 typical indications for IVC filters, and we would approach

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09:44:36 1 them and inform them, informed consent, inform them that we  
2 were doing this pilot study and they would be the first or  
3 early patients, the first ones to receive this new unknown  
4 filter. And we would discuss that with them, and then with  
09:44:54 5 their permission, proceed to place the filter, and monitor  
6 the patient, and then retrieve the filter.

7 Q Now, first of all, had you been using Bard filters before  
8 this study?

9 A Prior to this study I had used the Bard permanent filter.

09:45:12 10 Q Which was the Simon Nitinol filter?

11 A Yes.

12 Q And you understood that this was going to be a new device,  
13 this Recovery; is that correct?

14 A Yes.

09:45:20 15 Q And what was it about the Recovery that was the proposal  
16 that was new or different from the Simon Nitinol filter?

17 A The filter had a number of modifications in order to  
18 facilitate having the filter removed.

19 Q Pardon me?

09:45:38 20 A It had a number of modifications to allow the filter to  
21 be removed. The other filters on the market, the so-called  
22 standard permanent filters, are designed in a way that  
23 they're meant to go into the body and stay in the body, and  
24 there's not an easy way -- they're not designed to be  
09:45:54 25 removed. Where this new filter has a hook on it to be



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09:45:57 1 removed, it's got deformable hooks to allow it to be removed  
2 from the caval wall.

3 Q And how did you feel about that new filter?

4 A Well, the concept of a temporary retrievable IVC filter  
09:46:14 5 has been discussed, had been discussed sometime prior to

6 this, and certainly of great interest to the medical  
7 community. And we believe that, in concept, these filters  
8 provide great benefit to patients because that way, instead  
9 of having a filter in -- stay in the body for ten, 20 years,  
09:46:34 10 the filter can be removed.

11 Q And when approximately did the study start, begin?

12 A I'm sorry, can you repeat that.

13 Q When did the study start?

14 A I believe it was approximately 2000.

09:46:51 15 Q And where was the study conducted?

16 A It was conducted at my hospital, Mount Sinai Hospital.  
17 As time went on, there were some mergers between the downtown  
18 Toronto hospitals, and so it was conducted as well at Toronto  
19 General Hospital and Toronto Western hospitals, which were  
09:47:09 20 other hospitals that I worked at.

21 Q Now, you said that you had met with people from Bard and  
22 NMT and you underwent a -- you participated in a presentation;  
23 is that correct?

24 A That's correct.

09:47:28 25 MR. O'CONNOR: Gay, could you put up Exhibit 2090,

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09:47:31 1 please.

2 BY MR. O'CONNOR:

3 Q Dr. Asch, do you recognize Exhibit 2090?

4 A Yes. This is a copy of the PowerPoint presentation that  
09:48:11 5 was shown to me at the initial meeting that I attended in  
6 Boston.

7 MR. O'CONNOR: Move to admit Exhibit 2090.

8 MR. NORTH: No objection, Your Honor.

9 THE COURT: Admitted.

09:48:23 10 (Exhibit 2090 admitted.)

11 BY MR. O'CONNOR:

12 Q Now, who was present at the meeting in Boston, do you  
13 recall?

14 A I'm not sure I can recall all their names now. It was  
09:48:35 15 essentially a combination of people from Bard Canada and Bard  
16 USA and NMT. I can name a number of names, if you'd like.

17 MR. O'CONNOR: First of all, may I publish  
18 Exhibit 2090 to the jury, Your Honor?

19 THE COURT: Yes.

09:48:49 20 BY MR. O'CONNOR:

21 Q And, again, Dr. Asch, this is the first page. We will go  
22 through this.

23 Was a Robert Carr present?

24 A Robert Carr was present, yes.

09:48:59 25 Q Did you know a Dr. John Kaufman?

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09:49:02 1 A Yes, I knew of John's reputation, and he was there as  
2 well.

3 Q What about Dr. -- was it Morris Simon?

4 A Morris Simon was there as well.

09:49:15 5 Q Who is Dr. Simon?

6 A Dr. Simon was, I believe, the founder of Nitinol Medical  
7 Technologies, and his name, the Simon Nitinol filter, his  
8 name is on the Simon Nitinol filter, which is distributed and  
9 sold by Bard.

09:49:33 10 MR. O'CONNOR: Let's go to page 7 of the exhibit,  
11 Gay.

12 And, if you could, highlight the -- in that box  
13 Recovery filters that deal with vena cava filter, please.

14 BY MR. O'CONNOR:

09:50:01 15 Q So is this information that was provided to you, Dr. Asch,  
16 to introduce to you this new concept of a retrievable filter?

17 A Yes.

18 Q And it says: Same strengths as a permanent filter.

19 How was that presented to you?

09:50:19 20 A It was presented to me this filter was really a  
21 modification of a currently sold filter, the Simon Nitinol  
22 filter, and so it could act, then, both as a permanent  
23 filter, based on their presentation, as well as being  
24 removable. So it had the option, in their view, that it  
09:50:41 25 could be potentially a permanent filter and a removable

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09:50:45 1 filter.

2 Q And did Bard indicate to you that there had been any  
3 testing conducted that established in their mind that the  
4 Recovery was the same as, for example, the Simon Nitinol  
09:51:01 5 filter?

6 A No. This was their hope and, again, I was led to believe  
7 that ultimately appropriate scientific testing would be done  
8 in terms of larger clinical studies to substantiate their  
9 claim, their hope, their ultimate aim.

09:51:18 10 Q If you look below it says: Accurate placement, enhanced  
11 centering, and a small sheath.

12 Do you see where I'm reading?

13 A Yes, I do.

14 Q What does accurate placement mean in the world of IVC  
09:51:30 15 filters to an interventional radiologist?

16 A Well, any medical device we place, it is important to  
17 have the device go where we want it to go. There have  
18 historically been some filters where, perhaps as you're  
19 deploying it, it may jump or move a little bit. And,  
09:51:46 20 actually, the Simon Nitinol filter, the permanent filter, did  
21 sometimes do that and it wouldn't always end up exactly where  
22 we wanted, which could have some negative effect in terms of  
23 its function and its complications. Whereas this different  
24 filter design was much more accurate in terms of its  
09:52:02 25 placement. And when you deployed it, it would go where you

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09:52:06 1 wanted it to go.

2 Q And enhanced centering, what does that mean? Could you  
3 put that in the context of filters?

4 A So the IVC, we put these filters, these devices, into a  
09:52:17 5 tubular structure, and we want them to be centered. We want  
6 them to be aligned along the axis of the IVC in order to  
7 maximize function and reduce complication. And there's a lot  
8 of discussion in literature about filter tilts. And when a  
9 filter does tilt, there is more potential for a complication  
09:52:36 10 or filter failure. So enhanced centering, having the filter  
11 go where you want, centered along the axis, is important.

12 Q And then: Removable at 12 weeks -- 12 weeks.

13 What was the significance to that statement in this  
14 presentation?

09:52:53 15 A The significance of that was there already was in Canada  
16 a device that had been released for sale by another  
17 manufacturer that could be retrieved, but the retrieval  
18 window for that was in the order of ten to 14 days. So the  
19 advantage of this newly designed filter was that a  
09:53:13 20 retrievability at 12 weeks gives much more option in terms of  
21 patient care.

22 MR. O'CONNOR: Gay, go to page 9.

23 BY MR. O'CONNOR:

24 Q Now, Dr. Asch, maybe just to put some context in what  
09:53:34 25 we're going to talk about, if you could just refresh all of us

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on just a little anatomy and just tell us about the IVC, the vena cava.

A So the inferior vena cava is essentially the largest vein in the body, which brings the blood from the legs, lower extremities, the pelvis, the abdomen, back to the heart. So it's kind of the opposite of the artery where blood flows down the artery and out into smaller arteries. The vein has multiple small veins from structures draining into it, which brings blood back to the heart.

Q And a filter, what is its intent?

A As the name suggests, the filter is meant to filter out blood clots, particles larger than red blood cells, and stop them from going to the lungs where, if a large clump, a large piece of blood clot goes to the lungs, it can cause serious injury, shortness of breath, pain, and death.

Q Now, Bard, in its presentation, described the Recovery filter as having arms designed for centering and caudal migration resistance.

MR. O'CONNOR: Gay, can you highlight that.

BY MR. O'CONNOR:

Q Do you see where I'm looking?

A I do. Does the jury see that? Okay.

So the arms of the upper portion of the filter there, and you can see they look like almost sharp little pinpoint needles. So with a horizontal component, which is meant to

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09:55:10 1 align with the IVC and help keep the filter aligned along the  
2 IVC axis, and because they're a little bit pointy, not sharp  
3 like a needle, but a little pointy at the bottom of the arm,  
4 that is meant to reduce the likelihood of the filter migrating  
09:55:28 5 caudally, which means downwards, in a downwards direction,  
6 towards the feet.

7 Q And why is that important?

8 A Well, any time the filter moves, and movement in any  
9 direction can also include tilting, the filter then can  
09:55:41 10 become unstable. It's sensitive to new and different forces,  
11 which may then cause the filter to fracture or to fail.

12 Q So when a device company like Bard says its filter is  
13 migration resistant, what does that mean?

14 A Well, those are key words that radiologists like to hear,  
09:56:02 15 and it makes it sound like it's a good device, because I want  
16 the filter to be centered and I want the filter not to move.  
17 So that piques my interest, and that's why I was excited at  
18 this presentation and thought, wow, based on this  
19 information, this looks like something that would be good for  
09:56:20 20 my patients.

21 Q Now, in relation to the --

22 MR. O'CONNOR: Gay, scroll down to the next line.  
23 One size fits all.

24 No, previous page. I apologize. Go back to the page  
09:56:32 25 before. One size fits all. I'm sorry.

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09:56:39 1 MS. MENNUTI: Here?

2 MR. O'CONNOR: Yes, please.

3 BY MR. O'CONNOR:

4 Q The diameter of the vena cava, is that the same in all  
09:56:51 5 patients?

6 A No.

7 Q What is the range?

8 A Depending on the age, size, weight of the patient, the  
9 range can be from 5 to 8 millimeters up to 35 millimeters.

09:57:02 10 Q And does the vena cava distend or contract?

11 A Yes. The vena cava is a soft tissue structure made of  
12 very, very thin walls, very different than an artery that has  
13 thick muscular walls that typically don't change that much in  
14 diameter. So a cava can change quite a bit. It's subjected  
09:57:23 15 to a number of forces, both in terms of our -- when we lift,  
16 when we change position, when we become dehydrated. If we  
17 don't drink enough, the cava can get smaller. And, on the  
18 other side of the coin, if we do the opposite things, the  
19 cava can get larger, which has an impact, then, on the actual  
09:57:43 20 caval size.

21 Q And the vena cava, as it goes from the level of the  
22 kidneys upward, does it change in diameter at all?

23 A Yes. Typically, the closer you get to the heart, the  
24 larger the cava becomes. And so above the renal veins is the  
09:58:00 25 typical anatomic landmark that we use to place filters. As



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09:58:05 1 you get north of the renal veins, closer to the heart, the  
2 IVC becomes wider in diameter.

3 Q When Bard indicated that one size fits all, what did that  
4 mean to you?

09:58:19 5 A Just a bit of a generic statement. That's really the  
6 standard size for IVC filters. There's a few filters that  
7 are manufactured to be placed in cavas that are larger than  
8 28 millimeters. The majority of filters, the kind of  
9 industry standard is to make a filter that is meant to be in  
09:58:38 10 an average cava up to 28 millimeters.

11 MR. O'CONNOR: Go to the next page, Gay, page 10.

12 Page 10. There we go. And go ahead and highlight  
13 both those bullet points.

14 BY MR. O'CONNOR:

09:59:03 15 Q Now, Dr. Asch, according to this PowerPoint, it says:  
16 Hooks strong enough to resist migration, 50 millimeters of  
17 mercury in a 28-millimeter IVC.

18 Do you see where I read?

19 A Yes.

09:59:19 20 Q Did Bard explain to you anything about testing it had done  
21 in terms of migration resistance?

22 A They did show me some slides and briefly went through  
23 their testing process and made the statements, which I wasn't  
24 in a position to substantiate. I took them at their word.

09:59:41 25 They did testing, they provided this number of 50 millimeters

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1 of mercury. I didn't question that number. My assumption is  
2 that that is an IVC filter company, they knew what the  
3 standard was, they knew what number was important in order to  
4 resist migration.

5 Q And was there animal testing done that you're aware of?

6 A There was animal testing, but I believe the animal  
7 testing was predominantly with respect to does the filter  
8 cause damage to the cava wall and can the filter be removed.

9 So before moving from a bench top to humans, they did some  
10 animal testing with really, I think, the single question of  
11 can this filter be removed without causing caval injury.

12 MR. O'CONNOR: Gay, go to page 22.

13 BY MR. O'CONNOR:

14 Q It appears there was a discussion about testing on sheeps;  
15 is that -- sheep; is that right?

16 A That's correct.

17 Q And is that what you were just talking about? In other  
18 words, Bard never indicated to you -- there was no testing  
19 that you're aware of that tested whether the filter was  
20 migrating in a sheep; is that correct?

21 A I'm not aware of any animal testing other than can the  
22 filter come out.

23 Q So the testing on sheep was just limited to putting it in  
24 and taking it out.

25 A I believe so.

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10:01:17 1 MR. NORTH: Your Honor, I object. I think he's  
2 leading the witness.

3 THE COURT: Sustained.

4 BY MR. O'CONNOR:

10:01:23 5 Q What was your understanding of the purpose of the sheep  
6 study in terms of use of the filter?

7 A My understanding was it was simply to look at the safety  
8 of the device. Does the device cause caval injury, either  
9 while the filter is in position or during or after filter  
10:01:39 10 removal.

11 Q Now, in this document, it has said in different places  
12 12-week removal for the Recovery filter.

13 Do you see that?

14 A Yes.

10:01:50 15 Q What does that mean to you?

16 A Well, that meant they had demonstrated in an animal model  
17 that the filter could be removed after 12 weeks. Which is,  
18 again, different than the clinical practice of the, at that  
19 time, clinically available device which could only -- which  
10:02:10 20 the manufacturers had tested and was only removable up to ten  
21 to 12 days.

22 MR. O'CONNOR: Let's look at Exhibit Number 4330,  
23 please.

24 BY MR. O'CONNOR:

10:02:40 25 Q Do you recognize Exhibit 4330?

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10:02:56 1 A Yes.

2 Q What is Exhibit 4330?

3 A This is my initial letter to the director of the Health  
4 Protection Branch of Canada, giving him the background and  
10:03:11 5 information that I had in order to request permission to use  
6 the filter on compassionate grounds for this pilot study.

7 MR. O'CONNOR: Now, I move to admit Exhibit 4330,  
8 Your Honor.

9 MR. NORTH: No objection, Your Honor.

10:03:29 10 THE COURT: Admitted.

11 (Exhibit 4330 admitted.)

12 MR. O'CONNOR: May we publish to the jury?

13 THE COURT: Yes.

14 BY MR. O'CONNOR:

10:03:35 15 Q So, Dr. Asch, this letter's dated July 21, 1999. Did you  
16 meet with Bard and NMT on more than one occasion?

17 A Yes.

18 Q And were there more than one presentations given to you?

19 A As I recall, there was only a single formal presentation.  
10:03:55 20 The other meetings had to do with the logistics and how to  
21 move forward on accruing patients, following the patients,  
22 and technical aspects of the study.

23 Q Okay. In the second paragraph it says that you actually  
24 visited NMT's manufacturing facility and you had opportunity  
10:04:18 25 of inserting and removing devices in sheep models.

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:04:24 1 A That's correct.

2 Q When you say that you were satisfied that this is safe and  
3 efficacious device, what was that based upon?

4 A That was based on the word of the people from NMT and  
10:04:39 5 Bard. They gave me the presentation, they gave me the  
6 information, and I took them at face value and believed that  
7 they told me they had done the testing and told me the device  
8 was safe in their animal use and their bench top use. I  
9 believed what they told me.

10:04:58 10 Q And if you look down where you write to Dr. Freeland that  
11 the filter was found to with withstand 50 millimeters of  
12 mercury. Do you see what I'm talking about?

13 A Yes.

14 Q That was something Bard represented to you?

10:05:11 15 A Yes. Going back to the prior evidence of this  
16 submission, the prior document you just showed, I'm just  
17 repeating the information that was provided to me by Bard and  
18 NMT.

19 Q Did you assume that Bard had studied the anatomy and the  
10:05:30 20 dynamics of the vena cava before they came to you about this  
21 study?

22 A Yes.

23 Q And did you assume that their studies had -- and their  
24 testing had been to designed in a way to predict how the  
10:05:43 25 filter would act in real life?

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:05:45 1 A Yes.

2 Q Were those among the reasons that you agreed to do this  
3 study?

4 A Yes, absolutely.

10:05:56 5 Q So explain to the jury the study itself. You had how many  
6 patients initially?

7 A The initial published study had 32 patients in it.

8 Q And tell us how these patients participated in the study.  
9 Were they provided with Recovery filters?

10:06:21 10 A Yes.

11 Q And were these patients monitored?

12 A Yes. These patients were very closely monitored,  
13 according to a very strict protocol. They had regularly  
14 scheduled abdominal radiographs to assess the filter in terms  
15 of position and integrity, and those -- each of those imaging  
16 studies was personally reviewed by myself, even though their  
17 radiographs may have been reported by another radiologist.

18 In addition, I personally reviewed any imaging study that  
19 they had as part of their medical care, which may have been  
20 over and above the rigorous imaging follow-up that we had as  
21 part of the study.

22 Q So the patients that participated signed an informed  
23 consent?

24 A Yes, they did.

10:07:10 25 Q Did they understand that it was an experiment?

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

1 A Yes, they did.

2 Q And the patients that participated, did they receive  
3 Recovery filters?

4 A Yes, they did.

5 Q Was there in the protocol a plan as to how long the  
6 filters would be in patients before they were removed?

7 A Patients who were selected, part of the study protocol  
8 was to select patients specifically with a view to removing  
9 the filter. So anyone that we thought that we couldn't  
10 remove the filter or shouldn't remove the filter, wouldn't  
11 get -- wouldn't be entered into the study and wouldn't get  
12 this filter.

13 So the plan for the study, again, the pilot study to  
14 evaluate filter retrievability, was to place filters in  
15 patients with the view to retrieving 100 percent of them.

16 Q And how were the filters inserted or implanted in the  
17 patients?

18 A They were inserted using standard radiologic techniques.  
19 We put a needle in, put a wire in, put a tube in, inject the  
20 dye, check the anatomy, and then put the filter in.

21 Q Can you explain to the jury just quickly, briefly, the  
22 percutaneous procedure as to how Recovery filters are placed.

23 A Different people do things differently, obviously. So my  
24 standard of practice is to put the filter into the vein in  
25 the leg, femoral vein. So I use an ultrasound machine to

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:08:29 1 find the vein. I clean and diffuse the skin. I put a small  
2 needle into the vein. When I'm sure in the right place, I  
3 put a wire into the vein and I put a tube, a catheter, into  
4 the vein in order to inject X-ray dye to assess their  
10:08:43 5 anatomy. Is there a blood clot there? Is there anatomic  
6 abnormalities? I want to know where the renal vein is. I  
7 mentioned that briefly. I want to know where those are in  
8 order to know where to put the filter. And once I'm  
9 satisfied -- and measure the cava. Again, that is key, I  
10:08:58 10 want to be sure the cava is less than 28 millimeters.

11 So once I'm satisfied that it's safe and appropriate  
12 to place the filter, then using the device that comes in the  
13 package, the standard device, I just put the filter in and  
14 release it, all while watching with X-rays.

10:09:17 15 Q And then you place the filter in a specific location in  
16 the vena cava?

17 A Yes.

18 Q And then the next step was to wait a period of time --  
19 well, monitor the patients first during the course of the  
10:09:30 20 study.

21 And explain to us specifically how the patients were  
22 monitored.

23 A So the patients were monitored with abdominal radiographs  
24 every two weeks. So we all have X-rays when we have tummy  
10:09:44 25 pain, so we just took an X-ray of the patient's abdomen. And



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10:09:47 1 I would look at it to look at the filter, and we compare that  
2 with the X-rays I took when I was placing the filter.

3 So is the filter in the same place? Has it tilted?  
4 Has it moved? Has it fractured? Looking for those  
10:10:00 5 complications in order to identify a complication that may  
6 occur in an asymptomatic patient in order to identify it and  
7 deal with it before an asymptomatic complication becomes a  
8 clinical complication.

9 Q And then at some point the intent was to retrieve the  
10:10:19 10 filter?

11 A It was always the intent to retrieve the filter. This  
12 was not a long-term study.

13 Q And could you explain to the members of the jury how the  
14 Recovery was intended to be retrieved? Removed?

10:10:32 15 A So this was a -- we call it Iannella (phonetic) design,  
16 different than some of the other designs, so there was a  
17 little nub, if you remember seeing at the top of the filter  
18 on the last image, and there's, it's called a cone, it's  
19 almost like a space shuttle when it docks with the space  
10:10:50 20 station.

21 So through the vein in the neck. So the cone is at  
22 the top of the filter. So although I place the filter through  
23 the leg vein, because the cone is the top, I need to go  
24 through the vein in the neck. So same thing, put a needle in,  
10:11:02 25 wire in, tube in, and inject X-ray dye at the beginning,

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10:11:05 1 again, to be sure that I know where the filter is, look to see  
2 if there is any clot present in the filter, look to see if  
3 there's any reason that I can't safely take the filter out.

4 And all things being equal, when it's all safe, I put  
10:11:19 5 the special cone device down, essentially grab onto the  
6 filter, and then remove the filter through a sheath through a  
7 little tube that I've placed in the vein.

8 Q At some point in time in the study did you learn of any  
9 complications?

10:11:35 10 A Yes.

11 Q Tell the jury what you learned and how you learned it.

12 A So in Patient Number 9, again, I was reviewing -- he was  
13 quite an ill man. I was reviewing some radiographs that he  
14 had had outside of the study. So, again, I was paying very  
10:11:52 15 close attention to these patients. I noticed on his X-ray  
16 that his filter had moved, and that gave me great concern.

17 Q Moved in what direction?

18 A It had moved -- initially it moved down caudally, towards  
19 his feet, and then subsequently cranially, up towards his  
10:12:13 20 head.

21 Q Did you note how far it moved?

22 A Moved approximately 4 centimeters, which is about two  
23 inches.

24 Q And how did you feel when you saw that radiograph?

10:12:23 25 A I was very -- I was very concerned. I was concerned for

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10:12:26 1 two reasons. I was concerned because this is a brand-new  
2 filter never been used, and now in Patient Number 9 we have a  
3 complication, a filter migration, and because, as the  
4 filter -- as we discussed before, as the filter moves up  
10:12:42 5 towards the heart, the IVC becomes wider, so once it starts  
6 migrating, my concern was it would migrate further, migrate  
7 into his heart, migrate into his lungs, where it could  
8 ultimately kill him.

9 Q Did the patient that experienced this complication have  
10:12:57 10 any symptoms?

11 A No. He was completely asymptomatic, and this was found  
12 only because he was part of the study and only because I was  
13 personally reviewing all of his imaging studies.

14 Q What did you do when you saw the radiograph?

10:13:14 15 A I did a bunch of things. I can't remember exactly what  
16 order. The first thing I did was probably phone the  
17 patient's physician and made arrangements to have the filter  
18 removed. And then at some point I contacted the people from  
19 Bard and/or NMT to inform them of this complication and let  
10:13:33 20 them know what was going on. And then I subsequently, as per  
21 ethics protocol, I contacted my hospital ethics review board  
22 and I contacted Health Protection Canada, because this is an  
23 unexpected complication, unexpected potentially serious  
24 complication, and as a result of all those -- that event, the  
10:13:53 25 study was put on hold so that we could investigate.

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10:14:03 1 MR. O'CONNOR: Gay, would you please put up  
2 Exhibit 557.

3 Thank you, Gay.

4 BY MR. O'CONNOR:

10:14:35 5 Q Dr. Asch, do you recognize Exhibit 557?

6 A Yes, I do.

7 Q What is it?

8 A So this is an e-mail that I sent. I'm a bit unsure who I  
9 sent it to because it looks like it's been copied and pasted  
10:14:52 10 and forwarded a number of times. But essentially this is an  
11 e-mail that I sent to, I think, the ethics board to inform  
12 them of the complication that had occurred and outlined the  
13 plan that I had as to how I was going to deal with it.

14 Q So this --

10:15:11 15 MR. O'CONNOR: Your Honor, move to admit Exhibit 557.

16 MR. NORTH: No objection, Your Honor.

17 THE COURT: Admitted.

18 (Exhibit 557 admitted.)

19 BY MR. O'CONNOR:

10:15:27 20 Q Now, Dr. Asch, first of all, is this an e-mail that you  
21 authored?

22 A Yes, it is.

23 Q And it's an e-mail that was sent to whom?

24 MR. O'CONNOR: Oh, excuse me. May I publish to the  
10:15:39 25 jury, Your Honor?

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:15:40 1 THE COURT: Yes.

2 THE WITNESS: I believe it was sent to the Health  
3 Canada and to the ethics board. So this has been forwarded a  
4 number of times, so I can't really tell who exactly was it  
10:15:57 5 initially sent to.

6 BY MR. O'CONNOR:

7 Q Is it your belief that initially the e-mail went to the  
8 ethics board?

9 A Yes.

10:16:02 10 Q And why did you do that?

11 A Number one, because I was concerned about the safety of  
12 the device, and, number two, because I'm legally required  
13 under the auspices of a research study to inform the ethics  
14 board of a serious adverse complication.

10:16:23 15 Q Going on down in this letter, you explained your belief as  
16 to why the filter migrated.

17 Do you see that? It looks like it's the beginning of  
18 the second full paragraph.

19 A Yes. So I hypothesized that the filter had caught a  
10:16:46 20 large clot. We knew that there was a large clot in the  
21 filter when I removed the filter. So I hypothesized that the  
22 impact, the stress of catching that clot overwhelmed the  
23 strength of the hooks and caused the filter to migrate.

24 Q Now, did you tell Bard your concerns that this may be --  
10:17:06 25 that this complication was serious and could have resulted in

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

1 death to the patient?

2 A Yes, I did.

3 Q And what was Bard's response?

4 A They said they would investigate that filter, which was

5 returned to them, and there were a number of conversations we

6 had trying to decide what do we do. Does this one patient

7 out of nine filter migration represent a trend or is it an

8 isolated event? And how do we decide? Do we -- so there's

9 lots of discussion. We decided do we halt the study

10 permanently or continue on with the study.

11 Q Did Bard indicate to you that they were going to look into  
12 it?

13 A They did.

14 Q And was the study suspended?

15 A The study was suspended at that time, yes.

16 Q And was it resumed?

17 A It was resumed, yes.

18 Q And how did you -- how was it resumed?

19 A There were extensive conversations with Bard, NMT, but

20 it's my recollection that, in my view, the -- it was the

21 conversation I personally had with John Kaufman, an American

22 interventional radiologist and experienced in IVC filters,

23 and based on the discussion I had with him, we together

24 agreed that it was reasonable to proceed with caution, with

25 extra monitoring, and with patient information and consent,

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10:18:30 1 we would proceed to see if this was an isolated event or if  
2 this was going to happen again.

3 Q In Exhibit 559 -- excuse me, 557, you stated that, "I  
4 believe that the filter migrated due to the impact of the  
10:18:49 5 large thrombus and in doing so likely saved this patient's  
6 life."

7 Can you explain that statement, please?

8 A Well, a large thrombus has the potential to kill a  
9 patient. Some -- every patient has different sensitivity to  
10:19:03 10 thrombus, but a large clot could kill a patient. So this  
11 filter did its job, acted as a filter and trapped that  
12 thrombus, preventing it from going to the lungs. But at the  
13 same time the filter failed in that it migrated. So the  
14 filter didn't do its complete job and stay where I had placed  
10:19:21 15 it.

16 Q So earlier when we talked about it staying in place, being  
17 stable, is that what failed in this filter?

18 A Yes.

19 Q And I think you said that as the vena cava goes up towards  
10:19:42 20 the heart, it becomes larger in diameter.

21 A Yes, it did.

22 Q And why was that a concern?

23 A Because if the filter has already migrated, as the cava  
24 gets larger in diameter it doesn't have the same resistance,  
10:19:58 25 the force of legs that hooks out on the filter wall are going

## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:20:05 1 to be reduced, making it easier for that filter to migrate  
2 further.

3 Q Did you talk to Dr. Kaufman at all about this event?

4 A Yes, I did.

10:20:33 5 Q Tell us about that conversation.

6 A Well, he shared -- he mirrored and absolutely shared my  
7 concerns that this experience, this migration is very  
8 concerning. But, again, being uncertain as to what the true  
9 incidence or frequency of this was, he agreed that the  
10:20:57 10 device, in theory, still had potential benefit to patients at  
11 large, and with very close monitoring in my study and, again,  
12 as Bard had suggested initially, subsequently with a  
13 follow-up larger study, the hope is that we can identify the  
14 true incidence of these and other types of complications.

10:21:25 15 Q So you continued with the study?

16 A Yes.

17 Q Did you have any other complications?

18 A Yes.

19 Q Did you have any complications involving a fracture,  
10:21:39 20 Dr. Asch?

21 A Yes. There was Patient 33 who experienced a filter  
22 fracture, including an arm and a hook.

23 Q Tell us about that patient.

24 A So that filter was place into a young woman who was  
10:21:53 25 pregnant at the time, and similar to Patient Number 9, her



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1 filter complication was only noted by myself after I  
2 personally reviewed her imaging studies. And, again, the  
3 scenario was kind of similar. I found out the complication,  
4 the filter fractures in this case, and then made arrangements  
5 to have the filter removed as quickly as possible and, again,  
6 I contacted the authorities, the Health Protection Branch and  
7 my hospital ethics board, informing them of this  
8 complication, and I put the study on hold with the support  
9 and approval of those governing bodies.

10 MR. O'CONNOR: Gay, could you please put up  
11 Exhibit 559, please.

12 BY MR. O'CONNOR:

13 Q Dr. Asch, can you look at and identify Exhibit 559.

14 A Yes. This is a e-mail that I sent which describes the  
15 filter fracture.

16 Q And, Dr. Asch, was the study suspended after this?

17 A Yes, it was.

18 Q Again, is this something that you found when you were  
19 reviewing radiographs?

20 A Yes. So I reviewed a radiograph that had been reported  
21 normal by the regular diagnostic radiologists. I identified  
22 this only because this patient was in the study and I  
23 personally reviewed her imaging studies.

24 Q Did Patient 33 have any symptoms associated with the  
25 fractures?

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10:23:34 1 A She was asymptomatic as well.

2 Q Now, eventually did you -- did your involvement end in the  
3 study?

4 A Yes. So my -- well, the study came to an end, but I  
10:23:52 5 think prior to the study ending I had a change in career, if  
6 you will. I went from working for University of Toronto to  
7 working at the hospital where I am now.

8 Q And after the patient, I think that was Patient Number 9  
9 that had the migrating, cephalad migrating filter, and then  
10:24:16 10 the patient that had the fracture, did you have any

11 discussions with Bard about any concerns you had about the  
12 Recovery filter?

13 A Yes. So after each complication I had discussions with  
14 Bard and expressed my concern about the filter and repeated  
10:24:32 15 the fact that they had promised me from the get-go that there  
16 would be a long-term safety study performed on all aspects of  
17 the filter. And, again, my study, this study was simply a  
18 pilot program.

19 Q Did you tell them that whether you -- did you tell them  
10:24:51 20 that you did not feel that this filter, the Recovery, was  
21 ready to be put on the market?

22 A Yes, I did.

23 Q And did Bard -- did anybody from Bard respond to you that,  
24 yes, they understood your concerns and that there was going to  
10:25:06 25 be a long-term study?

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10:25:07 1 MR. NORTH: Objection, Your Honor. Leading.

2 THE COURT: Sustained.

3 BY MR. O'CONNOR:

4 Q What was -- did you receive a response about your concerns  
10:25:13 5 from anybody at Bard?

6 A It was my understanding they were going to do two things.  
7 One is look at the filter again, particularly with respect to  
8 the fracture, and see if there was a design issue that needed  
9 to be changed. And, again, always in the background, I was  
10:25:26 10 informed that a long-term study was going to be done.

11 Q And at some point in time did you learn whether a  
12 long-term study was done or not?

13 A I learned that a long-term study had not been done, but  
14 this device had been released for use -- for general use.

10:25:54 15 Q And how did you learn that?

16 A On the street. Just through word of mouth. I heard it  
17 from other radiologists who said, well, I just put this  
18 filter in. I said, oh, that's kind of strange, I didn't  
19 think the filter was released for use yet outside of a study.

10:26:12 20 Are you doing a study? The answer was, no, they sold me a  
21 filter.

22 Q How did you feel when you heard that?

23 A I felt betrayed, I felt frustrated, I felt concerned  
24 that, particularly given the two, what I consider serious

10:26:24 25 complications in my limited study, that the filter was now in

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1 fairly widespread use without plans for the study that I had  
2 initially been promised.

3 MR. O'CONNOR: Gay, could you please put up  
4 Exhibit 558.

5 BY MR. O'CONNOR:

6 Q Can you identify Exhibit 558, please.

7 A Yes. That is the scientific manuscript that I wrote and  
8 was published in the Journal of Radiology after completion  
9 of -- which included 32 patients in the study.

10 MR. O'CONNOR: Excuse me. Your Honor, I need to go  
11 back to Exhibit 559.

12 Gay, could you please put 559.

13 BY MR. O'CONNOR:

14 Q Dr. Asch --

15 MR. O'CONNOR: At this time I move Exhibit 559 into  
16 evidence.

17 MR. NORTH: No objection, Your Honor.

18 THE COURT: Admitted.

19 (Exhibit 559 admitted.)

20 BY MR. O'CONNOR:

21 Q Dr. Asch, is this a notification that you gave the board  
22 again about the fracture in Patient 33?

23 A Yes, it is.

24 Q And after this is when you suspended your study?

25 A Yes.

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10:27:44 1 MR. O'CONNOR: May I publish this to the jury,  
2 please?

3 THE COURT: Yes.

4 BY MR. O'CONNOR:

10:27:47 5 Q Dr. Asch, with Patient 33, like Patient 9, did you receive  
6 any indication that -- from Bard whether this incident would  
7 be looked into?

8 A Yes, they indicated that both incidents would be looked  
9 into.

10:28:20 10 Q Did you participate in any investigation?

11 A No, I did not.

12 Q And were you told at some point in time that the  
13 Patient 33 situation was investigated?

14 A Yes.

10:28:34 15 Q Did the study resume after that?

16 A Yes, it did.

17 Q All in all, how many patients participated in this study?

18 A I believe there were approximately 56.

19 MR. O'CONNOR: Let's display Exhibit 558.

10:28:48 20 BY MR. O'CONNOR:

21 Q And what is Exhibit 558?

22 A Again, that is the scientific manuscript that was  
23 published in the Journal of Radiology describing the results  
24 of the first 32 patients in this pilot study.

10:29:14 25 MR. O'CONNOR: One moment, Your Honor.

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10:29:20 1 THE COURT: We are at the 10:30 point, so we're going  
2 to break for the morning.

3 Ladies and gentlemen, we will resume at 10:45.  
4 Please remember not to discuss the case, and we will excuse  
10:29:29 5 the jury.

6 (Recess was taken from 10:29 to 10:45. Proceedings  
7 resumed in open court with the jury present.)

8 THE COURT: Thank you. Please be seated.

9 You may continue, Mr. O'Connor.

10:46:37 10 MR. O'CONNOR: Thank you, Your Honor.

11 BY MR. O'CONNOR:

12 Q Dr. Asch, your initial study I think you said involved  
13 thirty-some patients. 32?

14 A 32 patients were published as far as the initial study,  
10:46:51 15 yes.

16 Q Did actually more patients participate in your study?

17 A Yes.

18 Q During your study did you see other complications?

19 A Yes, I did. There were a number of complications, yes.

10:47:01 20 Q Did you, for example, see a number of procedural  
21 difficulties?

22 A Yes.

23 Q Were those recorded?

24 A Yes, they were.

10:47:07 25 Q Reported to Bard?

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1 A Yes.

2 Q Did you see tilts?

3 A Yes. There were possibly five filter tilts.

4 Q And tilt, for the jury, again, is what?

5 A Tilt is the filter is angled with respect to the caval  
6 axis, and for purposes of definition for this study, tilt was  
7 greater than 15 degrees.

8 Q And is there any risk or concerns about tilt as a filter  
9 failure?

10 A Yes. Tilt has potential serious complications, results,  
11 in terms of filter fracture, filter migration, and filter  
12 failure.

13 Q And what is that?

14 MR. NORTH: Your Honor, objection. No disclosure as  
15 an expert witness.

16 THE COURT: Overruled.

17 THE WITNESS: Can you repeat the question?

18 BY MR. O'CONNOR:

19 Q Sure. In terms of those risks, what are they?

20 A Filter fracture, potential migration, potential failure,  
21 which means the filter won't trap a clot and it can go to the  
22 lungs and cause injury or death.

23 Q And did you see perforation?

24 A Yes.

25 Q Was that a serious complication?

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10:48:17 1 A Yes, that's a potential serious complication.

2 Q You told us about the cephalad migration you saw in  
3 Patient 9.

4 A Yes.

10:48:25 5 Q And did you see caudal migration in patients?

6 A Yes.

7 Q Was that also in Patient 9?

8 A Yes.

9 Q You learned that the filter went down and then up.

10:48:35 10 A That's correct.

11 Q And is that a serious complication?

12 A Yes. Any filter movement is a potential serious  
13 complication.

14 Q And then you saw an arm fracture and a leg hook fracture  
10:48:46 15 in Patient 33?

16 A That's correct.

17 Q And that concerned you as well?

18 A Very much.

19 Q Is fracture a serious complication?

10:48:54 20 A Yes.

21 Q And what types of risks can that present to a patient?

22 A Well, that renders the filter unstable. The filter could  
23 then fail and allow blood clots to get to the lungs. The  
24 filter fragment could migrate to the heart or the lungs  
10:49:10 25 and/or the bulk of the filter could migrate to the heart or



## DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:49:14 1 the lungs, where it could cause serious problems.

2 Q In the patients where you observed these failure modes in,  
3 these are all on radiographs; is that right?

4 A Yes. These are all asymptomatic patients, detected on  
10:49:31 5 radiographs.

6 Q Asymptomatic. If a patient, from what you're experiencing  
7 in this study, had a failure that was asymptomatic, is that  
8 any reason that a doctor should not be concerned?

9 A No. I consider myself lucky when I find an asymptomatic  
10:49:48 10 problem, complication, of the filter or an asymptomatic mass  
11 in someone's pancreas because we like to identify it before  
12 it becomes symptomatic because once it's symptomatic it's  
13 often too late to avoid pain and suffering.

14 Q Let me switch gears on you, Doctor. Did Bard at any time  
10:50:17 15 ever indicate to you that they would use -- intended to use  
16 your study for purposes of establishing substantial  
17 equivalence for a 510(k) application to get it cleared by the  
18 FDA here in the United States?

19 A They never informed me of that, no.

10:50:38 20 Q If Bard had asked you, would you have given them  
21 permission?

22 A I would have denied permission because this study was,  
23 again, designed as a pilot study to assess retrievability of  
24 the device and was not meant to assess safety, long-term  
10:50:56 25 in-dwelling safety as a permanent filter. So this study

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1 would not be appropriate to -- for that submission.

2 Q Did Bard ever contact you and tell you that Bard intended  
3 to use your study to establish substantial equivalence for a  
4 510(k) application to get the Recovery cleared through the  
5 FDA?

6 A They never spoke with me about that.

7 MR. O'CONNOR: Gay, would you display Exhibit 5189,  
8 please.

9 And, Gay, would you turn to page 0029.

10 BY MR. O'CONNOR:

11 Q Dr. Asch, have you ever seen this document before?

12 A I believe I've seen it in prior court, but I had not seen  
13 it as part of my clinical practice or in conversation with  
14 Bard.

15 Q Have you ever seen a 510(k) application that included your  
16 study and made a statement that Dr. Asch's data relative to  
17 complications during filter placement, recurrent pulmonary  
18 embolism, death, filter migration, et cetera, provide clinical  
19 data to support a determination of substantial equivalence as  
20 a permanent filter?

21 A I was not aware of any of this at the time of the writing  
22 of this document.

23 Q And would you have authorized Bard to use or make any  
24 statement to the FDA?

25 A I would not have done so.

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:52:45 1 Q And if Bard did, what's your response?

2 A I would be disappointed and concerned because that opened  
3 the door towards the widespread use of a device that hadn't  
4 been appropriately tested and puts patients at risk.

10:53:03 5 MR. O'CONNOR: At this time I would move for  
6 admission of 5189, Your Honor.

7 MR. NORTH: No objection, Your Honor.

8 THE COURT: Admitted.

9 (Exhibit 5189 admitted.)

10:53:12 10 MR. O'CONNOR: Publish to the jury?

11 THE COURT: You may.

12 MR. O'CONNOR: Gay, could you please go back to the  
13 first page.

14 BY MR. O'CONNOR:

10:53:32 15 Q Dr. Asch, this document's entitled Recovery Filter System  
16 Special 510(k) Submission.

17 Do you see that?

18 A Yes, I do.

19 Q Are you knowledgeable or have any expertise in the  
10:53:45 20 clearance process of 510(k)?

21 A I have no knowledge or expertise in this area.

22 MR. O'CONNOR: Gay, turn to page 5189.0029, please.

23 In the third paragraph highlight "however." The  
24 sentence beginning "However," Gay, right there at the end.

10:54:18 25 All the way down. Thank you.

DIRECT EXAMINATION - MURRAY R. ASCH, M.D.

10:54:20 1 BY MR. O'CONNOR:

2 Q Dr. Asch, was your pilot study to study the  
3 implantability, retrievability, of the Recovery filter ever  
4 designed to or intended to establish substantial equivalence  
10:54:32 5 for the Recovery as a permanent filter?

6 A That was never the aim of the study. The study was not  
7 designed to do that.

8 Q And did you ever authorize Bard to represent to any  
9 government agency here in the United States that the purpose  
10:54:48 10 or the intent of your study to was establish substantial  
11 equivalence for clearance in the FDA?

12 A I would never have authorized this study to be used for a  
13 submission like this.

14 Q Why?

10:55:03 15 A The study wasn't designed for that. It's inappropriate  
16 to draw conclusions and make statements about a study when  
17 that wasn't the initial stated goal of a study. So my study  
18 didn't demonstrate this.

19 Q Your study was never intended to be any type of safety and  
10:55:22 20 efficacy study. Is that fair?

21 MR. NORTH: Objection. Leading.

22 THE COURT: Sustained.

23 BY MR. O'CONNOR:

24 Q Was your study intended to establish safety or efficacy?

10:55:32 25 A No. The single goal of the study was to establish

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 whether or not the filter could be safely retrieved.

2 MR. O'CONNOR: Thank you. No further questions.

3 THE COURT: Cross-examination.

4 MR. NORTH: Yes, Your Honor.

5 C R O S S - E X A M I N A T I O N

6 BY MR. NORTH:

7 Q Good morning, Dr. Asch.

8 A Good morning.

9 Q Your involvement with Bard that you have discussed today  
10 concerned the Recovery filter; is that correct?

11 A That's correct.

12 Q And your study was conducted in approximately the 2000 to  
13 2002 time frame; correct?

14 A That's correct.

15 Q And it only involved, that clinical study, the Recovery  
16 filter; right?

17 A Yes.

18 Q And, in fact, you have had no dealings with Bard, as I  
19 understand it, for 13 years, since 2005.

20 A That's incorrect. I and -- my department and I use  
21 other -- I use a variety of Bard products, so I've got a  
22 regular relationship with Bard.

23 Q But you have had no relation -- you have not spoken with  
24 anybody at Bard about filters since 2005, have you?

25 A No, my sales representatives constantly come around and

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 show me the new filters and we talk about filters all the  
2 time.

3 Q But you have done no studies for Bard at all since 2000 --  
4 since this study in 2002; correct?

5 A That's correct. I have done no studies since that time.

6 Q And you have not been involved at all in the development  
7 of the G2 filter, were you?

8 A That's correct.

9 Q And you did not conduct any study of the G2 filter, did  
10 you?

11 A That's correct.

12 Q And you have not had any involvement with Bard in the  
13 development of its third generation retrievable filter, the  
14 G2X, have you?

15 A That's correct.

16 Q And you did not conduct a clinical study regarding the G2X  
17 filter; correct?

18 A That's correct.

19 Q And, similarly, you've had no involvement with Bard in the  
20 development of the Eclipse filter that was introduced to the  
21 market in 2010; correct?

22 A That's correct.

23 Q And you did not conduct any clinical study on the Eclipse  
24 filter that was the model of filter implanted in Ms. Jones,  
25 did you?

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

10:57:54 1 A That's correct.

2 Q And, in fact, as I understand it, you have not even used  
3 in your practice a Bard filter since approximately 2005;  
4 correct?

10:58:06 5 A That's correct.

6 Q Now, you flew from eastern Canada to Phoenix to testify  
7 here today; correct?

8 A Yes, I did.

9 Q My understanding is you said you were going to be paid  
10:58:33 10 \$5,000 a day for your time?

11 A Yes.

12 Q And that your involvement to come here today to testify  
13 will be a total of four days?

14 A Four. Equivalent of four days of missed work.

10:58:48 15 Q So you are going to be charging the plaintiffs \$20,000 for  
16 this court appearance?

17 A I'm charging the same amount I charge for any testimony  
18 or involvement with any other company I've worked with.

19 Q And for this particular appearance, that is \$20,000;  
10:59:07 20 correct?

21 A Yes, that is what I'm charging. Yes.

22 Q In fact, you have appeared to testify for these  
23 plaintiffs' attorneys in the past; correct?

24 A That's correct.

10:59:17 25 Q And each time you have appeared to testify for these

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

10:59:21 1 attorneys, you have charged either \$5,000 a day or 6- or \$700  
2 an hour; correct?

3 A That's the standard rate I've charged for the last 15  
4 years of my practice.

10:59:36 5 Q And as early as 2013, you consulted with Mr. Lopez on the  
6 plaintiff's team to prepare a declaration in another matter  
7 pending in California; correct?

8 A Yes.

9 Q And in working -- in consulting with Mr. Lopez in that  
10:59:54 10 case, you likewise charged your normal rate of \$5,000 a day or  
11 6- or \$700 an hour; correct?

12 A My charges are consistent for anyone I work with.

13 Q As I understand it, while you continue to utilize IVC  
14 filters, you have not published any article concerning IVC  
11:00:17 15 filters since at least 2005; correct?

16 A That's correct.

17 Q And over the years you've also done some consulting work  
18 with one of Bard's competitors that also makes IVC filters,  
19 the Cook Medical Group; correct?

11:00:40 20 A Yes. I consult and continue to consult with a number of  
21 different device companies.

22 Q And that includes Cook concerning their competitive  
23 filters; correct?

24 A It does, yeah.

11:00:51 25 Q And you have performed studies for Cook regarding their



## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:00:54 1 filters; correct?

2 A I have performed studies for many different medical  
3 device companies, yeah.

4 Q Now, when you first became involved with the Recovery  
11:01:11 5 filter and NMT, Nitinol Medical Technologies, you met with  
6 Dr. Morris Simon; correct?

7 A Yes.

8 Q And Dr. Simon was the inventor of the Simon Nitinol  
9 filter, wasn't he?

11:01:24 10 A That's my understanding, yes.

11 Q And you've utilized I believe, as you told us, the  
12 Simon Nitinol filter as a part of your practice?

13 A Yes, I did.

14 Q But it did not have the added benefit of being a  
11:01:38 15 retrievable filter; correct?

16 A That's correct.

17 Q And did you consider the use of a retrievable filter to be  
18 a positive development in the medical options you had to treat  
19 patients?

11:01:51 20 A Yes. I believe that temporary filters have great  
21 benefits to patients.

22 Q Now, during the course of your work on this study  
23 concerning the Recovery filter, you worked very closely with  
24 Mr. Rob Carr from Bard; correct?

11:02:11 25 A Yes, that's correct.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:02:13 1 Q And I believe, as you have told us before, you consider  
2 Mr. Carr to be helpful, supportive, creative, and having  
3 everybody's best interest in mind; correct?

4 A That has been my belief, yes.

11:02:26 5 Q And I believe you also told us that you considered him to  
6 be a man of great integrity.

7 A That was my impression, yes.

8 Q Your initial study, as I understand it, involved 32  
9 patients; correct?

11:02:44 10 A That was the initial published study, yes.

11 Q But you continued to look at patients and ultimately, as a  
12 part of the formal study, implanted the device in 58 total;  
13 correct?

14 A Yes. Correct.

11:02:59 15 Q And after implanting in 58 patients, you continued  
16 yourself to utilize the Recovery filter in additional patients  
17 as part of your practice for a while; correct?

18 A Yes, I did.

19 Q And so is it fair to say that you probably implanted the  
11:03:18 20 Recovery filter in as many as 80 patients?

21 A No. I would say after I left the study, after I left  
22 Mount Sinai Hospital, it was probably on the order of ten  
23 filters.

24 Q So between 65 and 70 total?

11:03:36 25 A I wasn't the one who inserted all the filters. Part of

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:03:40 1 the study I had a colleague who worked with me.

2 Q Well, as part of your study, you at least were familiar  
3 with 58 patients that received the Recovery filter, whether  
4 you personally implanted the device or not; correct?

11:03:52 5 A That's correct.

6 Q And then you implanted it in your own practice in an  
7 additional ten paying patients or so?

8 A Yes.

9 Q So approximately 68 total patients with the Recovery  
11:04:02 10 filter you were familiar with.

11 A Yes.

12 Q And of those 68, there was only that one incident of  
13 fracture; correct --

14 A That --

11:04:13 15 Q -- one patient?

16 A Yes.

17 Q Of those 68, there was only that one incident of  
18 migration; correct?

19 A That I'm familiar with. Again, I left the hospital so I  
11:04:24 20 don't have follow-up information on the patients after I  
21 left.

22 Q But based on what you know as you sit here today, out of  
23 the 68 patients that you were familiar with and worked with,  
24 only one had a migration and only one had a fracture; correct?

11:04:43 25 A Yes.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:04:45 1 Q And you mentioned this with Mr. O'Connor. Both the  
2 patient that had the fracture and the patient that had the  
3 migration were asymptomatic; correct?

4 A Yes, they were.

11:05:01 5 Q That means they didn't have any pain, any visible injury,  
6 anything that made them aware of any complication in that  
7 filter.

8 A Yes, which can be a good thing or a dangerous thing.

9 Q But, in other words, neither of those patients suffered  
11:05:18 10 any physical pain because of the complication with their  
11 filter.

12 A They did not suffer because I was able to intervene and  
13 remove the filter prior to them becoming symptomatic.

14 Q Patient 33 was the patient who had had the fracture;  
11:05:48 15 correct?

16 A Yes.

17 Q And I believe that was a woman who was pregnant at the  
18 time?

19 A That's correct.

11:05:53 20 Q And did you have any suspicion or belief in investigating  
21 that incident that her pregnancy or childbirth may have had  
22 some relationship to the fracture?

23 A Well, I think in some of the e-mails that I had sent, I  
24 think I alluded to that. But on the other hand, filters are  
11:06:13 25 placed in pregnant patients on a widespread basis and yet

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 filter fractures outside of this device had been previously  
2 uncommon to the point I've never seen them.

3 Q After you completed the study or left the hospital in  
4 Toronto and went into the private practice, you were no longer  
5 participating with Bard in the formal study; correct?

6 A That's correct.

7 Q And because of that, you were under no contractual  
8 obligation to continue placing Recovery filters; correct?

9 A That's correct.

10 Q So when you placed that additional ten filters as part of  
11 your practice, you did so knowing that no long-term safety and  
12 efficacy study had been performed; correct?

13 A That's correct.

14 MR. NORTH: If we could look at Exhibit 556, which  
15 has been previously admitted.

16 Your Honor, if we could display that to the jury?

17 THE COURT: You may.

18 MR. NORTH: Thank you, Your Honor.

19 And if we could turn to page 5 of this exhibit.

20 BY MR. NORTH:

21 Q This is the exhibit that Mr. O'Connor discussed with you  
22 as a part of your direct examination; correct?

23 A Yes. Correct.

24 Q And this is the protocol for the study that you conducted  
25 with regard to the Recovery filter; is that correct?

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:07:59 1 A That's correct.

2 Q And if we could look at the first paragraph under the  
3 section Background.

4 In the protocol for the study, it was recognized that  
11:08:16 5 long-term complications such as filter strut failure or  
6 perforation cause hesitancy to use these devices in children  
7 and young adults; correct?

8 A Correct.

9 Q And it talked about the need to develop a filter that  
11:08:36 10 could be left in longer than just a week or two; correct?

11 A Yes.

12 Q In fact, it says currently temporary or retrievable  
13 devices must be removed prior to two weeks post insertion.

14 A Yes.

11:08:55 15 Q And then concludes by saying that without -- with this  
16 very narrow window, relatively few patients are truly  
17 candidates for temporary filters; correct?

18 A Correct.

19 Q And so that was one of the benefits of the Recovery  
11:09:10 20 filter, it was going to be the first filter available to  
21 doctors that could be left in for an extended period of time  
22 and then still retrieved; correct?

23 A That's correct.

24 MR. NORTH: If we could look at Exhibit 557, which I  
11:09:51 25 believe has been previously admitted, and I would ask this be

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 published to the jury.

2 THE COURT: You may.

3 BY MR. NORTH:

4 Q As you mentioned earlier in that second paragraph, you  
5 believe that this filter, even though it -- the paragraph  
6 below that, I'm sorry -- even though it migrated, you believed  
7 it did so because of a large thrombus or clot; is that  
8 correct?

9 A That was my belief, yeah.

10 Q And you believed it likely saved the patient's life.

11 A Potentially, yes.

12 Q And you go on a couple of lines down to note that "I  
13 believe that this is an isolated event and that filter  
14 migration is a known complication of all currently approved  
15 devices." Correct?

16 A Correct.

17 Q Now, Mr. Rob Carr, who we talked about a few moments ago,  
18 he was involved in the investigation of this event; correct?

19 A Yes.

20 Q Now, and this event was reported to authorities or the  
21 administration at the hospital you worked in; correct?

22 A That's correct.

23 Q And it was reported to the Canadian authorities from whom  
24 you had obtained permission to conduct this study?

25 A That's correct.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:11:32 1 Q And after the investigation was concluded and reported to  
2 the Canadian authorities, they permitted you to continue the  
3 study; correct?

4 A Yes.

11:11:40 5 Q And you were willing to do so; correct?

6 A With the proviso that patients were informed and there  
7 was more rigorous follow-up.

8 Q As we just saw when looking at this protocol, before you  
9 ever started this study, filter fracture was a known  
11:12:02 10 complication of IVC filters; correct?

11 A Yes.

12 Q And as you did with the migration, when the fracture  
13 occurred in Patient Number 33, you reported that to the  
14 authorities at your hospital; correct?

11:12:16 15 A That's correct.

16 Q And you reported it to the Canadian regulatory authorities  
17 that had given you permission to conduct this study?

18 A That's correct.

19 Q Are you aware that NMT or Bard conducted an investigation  
11:12:45 20 of that incident?

21 A They informed me they were going to do so.

22 Q And did they inform you of the results of that  
23 investigation?

24 A Of the fracture?

11:12:53 25 Q Yes.



## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:12:53 1 A Yes. It was my understanding that that investigation  
2 concluded that there, I'll say, was an issue with respect to  
3 the welding of the device and they were going to make changes  
4 in the device manufacturing process.

11:13:08 5 Q Didn't -- did they also tell you or were you aware that  
6 their investigation concluded that the natural anatomy,  
7 anatomical forces of labor and childbirth precipitated the  
8 fracture of the filter?

9 A I'm not sure their investigation was targeted to make  
11:13:31 10 that conclusion. Again, IVC filters are placed commonly in  
11 pregnant women and they don't typically fracture.

12 Q Do you -- are you aware of the fact that after they  
13 concluded their investigation with this and before they ever  
14 began selling the Recovery filter on the market, they revised  
11:13:49 15 the instructions for use to give specific instructions to  
16 doctors as to how to place the filter, if they chose to do so,  
17 in a pregnant woman?

18 A I have become aware of that document and those are the  
19 instructions that are the standard instructions for any IVC  
11:14:06 20 user for any other device in pregnant women.

21 Q Well, are you aware of the fact they made that change to  
22 their instructions for use specifically based on the  
23 investigation they conducted of the incident in your study?

24 A I'm aware they revised the instructions for use.

11:14:32 25 MR. NORTH: If we could bring up Exhibit 558, please.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:14:35 1 BY MR. NORTH:

2 Q Mr. O'Connor briefly started discussed this publication  
3 with you. Do you recall this publication?

4 A Yes, I do.

11:14:48 5 Q And, in fact, you are the author of this publication;  
6 correct?

7 A Yes, I am.

8 Q And it is entitled Initial Experience in Humans with a New  
9 Retrievable Inferior Vena Cava Filter?

11:15:04 10 A Yes.

11 Q And this was published in the medical journal called  
12 Radiology in 2002; correct?

13 A Yes.

14 Q And you're familiar with the medical journal Radiology?

11:15:15 15 A Yes, I am.

16 Q I believe, if you look over on the left, you initially --  
17 on the first page, initially submitted this to the journal in  
18 November of 2001; correct?

19 A Yes.

11:15:31 20 Q And a couple of months later, the editors of the journal  
21 specifically asked you to revise this; correct?

22 A Yes, that's correct.

23 Q And you would agree that the journal, medical journal  
24 Radiology, is a well-respected authority in your particular  
11:15:54 25 field; correct?

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:15:55 1 A Yes.

2 Q It publishes peer-reviewed articles written by doctors  
3 like yourself who are reporting on studies or observations  
4 they have made in their practices?

11:16:04 5 A Yes.

6 Q And people in your field rely upon journals like  
7 Radiology; correct?

8 A Yes, they do. We all do.

9 Q Now, at this time when you published this article, you're  
11:16:17 10 publishing it on the first 32 patients in your study; correct?

11 A Yes.

12 MR. NORTH: If we could look at page 843.

13 BY MR. NORTH:

14 Q In looking in the middle paragraph, Dr. Asch, middle  
11:16:54 15 column, you note for the readers in the Radiology journal that  
16 there was a single occurrence of asymptomatic filter migration  
17 in this series of 32 patients; correct?

18 A That's correct.

19 MR. NORTH: And then if we could turn to the final  
11:17:14 20 page and the final paragraph.

21 BY MR. NORTH:

22 Q Dr. Asch, in this study -- in this article, you state, and  
23 let me quote, "In conclusion, this preliminary, special-access  
24 use of the RNF," Recovery filter, "a retrievable IVC filter,  
11:17:43 25 suggests that the filter can easily be delivered via a femoral

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:17:48 1 vein." Correct?

2 A Yes.

3 Q And you further note it can be removed percutaneously up  
4 to 134 days after insertion; correct?

11:18:02 5 A Yes.

6 Q And then --

7 MR. NORTH: If we can show the whole paragraph there.  
8 No -- that's fine. I'm sorry.

9 BY MR. NORTH:

11:18:13 10 Q And then you state -- in conclusion in this article you  
11 state, "No substantial complications were encountered in this  
12 series." Correct?

13 A Well, I did say that, but at the top of that paragraph it  
14 clearly says "preliminary study" and "suggests that." Which,  
11:18:35 15 again, in my mind, support the initial feeling that this was  
16 a preliminary study meant to pave the way for a long-term  
17 study.

18 Q But even after telling your readers and the readers of  
19 this author -- this article, that there had been a migration,  
11:18:55 20 the migration you talked about with Mr. O'Connor, you  
21 published in this journal "No substantial complications were  
22 encountered in this series." Correct?

23 A Yes, that was what was written.

24 MR. NORTH: Let's look, if we could, at Exhibit 555.  
25

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 BY MR. NORTH:

2 Q This is another article or letter to the editor to a --  
3 excuse me, to a medical journal that you wrote; correct?

4 A Correct.

5 Q And you are one of four authors of this letter; is that  
6 correct?

7 A Yes, I am.

8 Q And the other three authors are -- were colleagues of  
9 yours at the University of Toronto; is that right?

10 A Yes.

11 Q And what journal was this published in?

12 A I think was that the Journal of Thrombosis and  
13 Haemostasis.

14 Q Do you consider that a reliable journal?

15 A Yes, I do.

16 Q Is it one you consult on occasion in your practice?

17 A Yes.

18 Q And does it publish peer-reviewed articles and other case  
19 reports?

20 A Yes, it does.

21 Q In this particular letter to the editor of this journal,  
22 it's entitled Temporary Inferior Vena Caval Filter Use in  
23 Pregnancy; correct?

24 A Yes.

25 Q And you talk in this article about Patient Number 33 who

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:20:53 1 had the fracture; correct?

2 A Yes.

3 MR. NORTH: And if we could go over to the second  
4 page, please, in the right column, the paragraph beginning  
11:21:03 5 "There."

6 BY MR. NORTH:

7 Q After telling the readers in this letter about Patient  
8 Number 33, the pregnant woman in your study, and the fracture  
9 of her filter, you and your colleagues stated there was --  
11:21:19 10 "There were no significant complications in the use of the IVC  
11 filter in our patients." Correct?

12 A In this limited series of 58 patients, yes.

13 Q So even though in that 58 patients you had this migration  
14 you talked about and you had this fracture that you talked  
11:21:40 15 about, you are telling the medical community that you did not  
16 consider those to be significant complications; is that  
17 correct?

18 A Yes. And I have to say I feel embarrassed by these  
19 things, and I have to say these articles were written to help  
11:21:59 20 pave the way towards a longer term big study, and that's why  
21 I wrote them. And I would have -- I sadly downplayed the  
22 complications that did occur that are significant. And,  
23 again, those were stated simply to facilitate a bigger study.

24 Q So you're telling us that you believe those complications  
11:22:22 25 to be significant but you downplayed them, as you just said,

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:22:25 1 to the medical community?

2 A Well, they were downplayed because early on experience  
3 with only 58 patients we don't know, with those complications  
4 in 58 patients, two complications in 58, is that the sign of  
11:22:41 5 worse things to come in the future with more widespread use  
6 of the device?

7 Q After talking about the filter fracture, you stated that  
8 this is a commonly accepted complication of IVC filters; is  
9 that correct?

11:22:58 10 A Yes. If you read the literature, IVC filter fracture is  
11 listed as a complication. But in my experience prior to this  
12 and in 20 years of practice before and after this, I have  
13 never seen a filter fracture personally.

14 Q And your colleagues go on to report that fracture has been  
11:23:18 15 previously reported with the Simon Nitinol filter in up to  
16 14 percent of patients; correct?

17 A That is what it says there, yes.

18 Q In talking about Patient Number 33, the pregnant woman  
19 whose filter had fractured, you noted that she remained  
11:23:45 20 asymptomatic for 18 months following the filter removal;  
21 correct?

22 A Yes. She was asymptomatic because the filter had been  
23 removed.

24 Q And then you go on in this article to the medical  
11:23:59 25 community and talk about the filter migration incident; right?

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:24:01 1 A Yes.

2 Q Patient 9.

3 A Yes.

4 Q And you told the medical community there was a minimal  
11:24:10 5 degree of filter migration in the second case which had no  
6 clinical consequences; correct?

7 A Yes.

8 Q And so after this study has been completed and even though  
9 you've had this fracture and even though you've had this  
11:24:29 10 migration, you tell the medical community that these were not  
11 significant complications, that the fracture patient remained  
12 asymptomatic, and that the migration patient had no clinical  
13 consequences; correct?

14 A Yes. I've already apologized for those statements. But  
11:24:48 15 at the end of this I did clearly state that follow-up  
16 abdominal imaging is essential to ensure that there is no  
17 more serious clinical complication.

18 MR. NORTH: Okay. If we can go down to the final  
19 paragraph, please.

11:25:08 20 BY MR. NORTH:

21 Q Towards the end of this you conclude and you tell the  
22 medical community in this letter, or article, that "The novel  
23 Recovery filter device is an attractive option when peripartum  
24 circumstances might extend the duration during which caval  
11:25:33 25 interruption should be maintained"; correct?



## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:25:35 1 A Yes.

2 Q By that you mean in pregnant women; is that correct?

3 A In this particular case, yes.

4 Q You're telling the medical community this device is an  
11:25:49 5 attractive option for pregnant women, already knowing you had  
6 one incident of fracture and one incident of migration in your  
7 study?

8 A Yes. But, again, these are articles that are written  
9 with the understanding Bard was going to perform a larger  
11:26:03 10 study and not rely on a case -- case reports from 58  
11 patients.

12 Q But you didn't say that in this article, did you?

13 A And I apologize for that.

14 Q And you just told the medical community that despite your  
11:26:18 15 experience or based on your experience in your study, you  
16 thought this was a viable attractive option for use in  
17 patients; correct?

18 A I did say that.

19 Q Now, you testified earlier, Dr. Asch, that you did not  
11:26:38 20 know that Bard was going to cite your study to the FDA;  
21 correct?

22 A For substantial equivalence for a permanent filter, yes.

23 Q You have no evidence that Bard misrepresented any aspect  
24 of your study to the FDA; right?

11:26:58 25 A My study wasn't meant to demonstrate permanent safety.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:27:02 1 Q That was not my question, Doctor.

2 You have no evidence or reason to believe that Bard  
3 misrepresented anything about your study to the FDA.

4 A Well, the document that has been previously entered as an  
11:27:17 5 exhibit makes -- makes an unsubstantiated claim referring to  
6 my study, so, yes, that is evidence.

7 Q Are you aware of the fact that Bard advised the FDA of the  
8 fracture incident in your study?

9 A No.

11:27:35 10 Q Are you aware of the fact that Bard advised the FDA of the  
11 migration incident in your study?

12 A I'm not aware of what Bard has communicated to the FDA.

13 Q Are you aware that Bard, in the instructions for use  
14 provided to every physician who bought the Recovery filter  
11:27:55 15 after your study was completed, that they described your study  
16 in the instructions for use?

17 A I believe I'm aware of that.

18 Q And are you aware that in the instructions for use, Bard  
19 told physicians who were using this filter that in your study  
11:28:15 20 there had been a report of one fracture incident?

21 A I believe I recall that.

22 Q And are you aware that in the instructions for use  
23 provided to every doctor who purchased this or used this, it  
24 referenced the one migration incident in your study?

11:28:34 25 A I believe so.

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:28:49 1 MR. NORTH: If we could bring up Exhibit 567.

2 BY MR. NORTH:

3 Q Are you familiar with Exhibit 567?

4 A Yes.

11:29:02 5 Q This is a letter that you wrote and signed; correct?

6 A Yes, it is.

7 Q And it was written under your letterhead or stationery  
8 from Mount Sinai Hospital in Toronto; correct?

9 A Yes.

11:29:20 10 Q And did you maintain this letter as a part of your files  
11 at Mount Sinai?

12 A Yes. When was I was at Mount Sinai.

13 Q And did you prepare this letter as a regular part of your  
14 business or work or practice as a radiologist consulting and  
11:29:40 15 performing studies?

16 A As a regular part, no. I was specifically asked to  
17 provide this letter by Bard.

18 Q But you would prepare communications for various people as  
19 a routine part of your work as a consultant or conducting  
11:29:55 20 studies of various sorts; correct?

21 A I have never been asked and I have never provided a  
22 letter of support for any portion of an approval process for  
23 any government agency.

24 Q But that's what this letter is, isn't it? It's a letter  
11:30:10 25 of support for a -- to a government agency; correct?

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 A Yes, it is.

2 MR. NORTH: Your Honor, at this time we would tender  
3 Exhibit 567.

4 MR. O'CONNOR: No objection.

5 THE COURT: Admitted.

6 (Exhibit 567 admitted.)

7 MR. NORTH: Could we display to the jury, Your Honor?

8 THE COURT: Yes.

9 BY MR. NORTH:

10 Q This letter was written on March 10 of 2003. Dated then;  
11 correct?

12 A Yes.

13 Q And if we could look at the first paragraph.

14 You state "It is with great pleasure that I write  
15 this letter in support of Bard's application for approval of  
16 its Recovery IVC filter system." Correct?

17 A I try to be polite in my letters, yes.

18 Q I'm sorry, what?

19 A I try to be polite in my letters.

20 Q And at the time you wrote this on March 10 of 2003, you  
21 had already completed your study of 58 patients; correct?

22 A Yes.

23 Q And you had already observed the migration incident and  
24 the fracture incident; correct?

25 A Yes.

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:31:35 1 Q And you knew that this letter was going to be provided or  
2 utilized with the United States Food and Drug Administration  
3 as a part of Bard's application; correct?

4 A Yes. I believed it was an application for use as a  
11:31:50 5 retrievable device, not as a permanent device.

6 MR. NORTH: Let's look at the paragraph towards the  
7 bottom that begins "I strongly believe."

8 BY MR. NORTH:

9 Q After completing your study, you wrote in a letter that  
11:32:12 10 you knew that Bard was going to submit to the FDA, and I  
11 quote: I strongly believe that the development of this  
12 retrievable IVC filter represents one of the most important  
13 advances in the field of interventional radiology in the past  
14 20 years; correct?

11:32:30 15 A Yes.

16 Q And you further stated "I further believe that this filter  
17 will positively change the way we treat patients with venous  
18 thromboembolic disease, a common affliction with significant  
19 impact on morbidity and mortality of our nation." Correct?

11:32:50 20 A Yes.

21 Q Even after completing your study and even knowing a  
22 long-term study that you talked about had not been undertaken,  
23 you put in this letter for government authorities there is a  
24 definite need for this device to be readily available to  
11:33:12 25 patients in Canada; correct?

## CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:33:16 1 A Yes. There is definite need and there is great potential  
2 for benefit. But, again, all of that is based upon a study  
3 demonstrating true safety of the device, and that was the  
4 intention of this letter.

11:33:28 5 Q You did not tell -- in this letter say a word about  
6 conditioning your approval or your support of this device  
7 until such time as an additional clinical study had been  
8 performed; correct?

9 A That's correct.

11:33:42 10 Q And, in fact, in the final paragraph you advised the  
11 government authorities, "I would be most happy to meet with  
12 you to further discuss my experience with this filter, and to  
13 answer any questions or concerns that you may have." Correct?

14 A Yes.

11:34:03 15 Q So, Dr. Asch, you knew that Bard was going to cite your  
16 study to the FDA in its application for clearance for this  
17 device; correct?

18 A It was my understanding they were going to use it as a  
19 temporary device to pave the way for the study that we had  
11:34:20 20 talked about from the beginning.

21 Q But you didn't mention that understanding in this  
22 endorsement letter, did you?

23 A That's correct. I, at this point, so many years later, I  
24 don't recall what extent of coaching may or may not have  
11:34:37 25 occurred. The letter is really fairly vague. It's

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 enthusiastic in support of the concept of the device, and  
2 looking at it now, there are different words that I probably  
3 should have used. But this is the letter.

4 Q You told us earlier you were downplaying your concerns in  
5 articles distributed to the medical community worldwide. Were  
6 you also downplaying your concerns to the federal and Canadian  
7 governmental authorities?

8 A Again, downplaying may be a bit of an overstatement. I  
9 was tempering them based on the potential benefit of the  
10 device. Again, always in the background of the belief that a  
11 long-term study was going to be done, and I didn't want to  
12 jump to any conclusions and end the potential use of this  
13 device without a proper study. The study I did was not meant  
14 to detect complete safety of this device.

15 Q But nowhere in this letter, Exhibit 567, did you tell the  
16 government that you believed a longer term study needed to be  
17 conducted before this device was readily available to  
18 patients; correct?

19 A I neglected to say that, that's correct.

20 THE COURT: Redirect.

21 MR. O'CONNOR: May we approach?

22 THE COURT: Yes.

23 If you want to stand up, ladies and gentlemen, while  
24 we talk for a minute, feel free.

25 (Bench conference as follows:)

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:36:26 1 MR. O'CONNOR: Your Honor, I believe the defense has  
2 opened the door. It made a big deal what he did after the  
3 study and the fact of the matter is he's not been able to tell  
4 his entire story that he stopped using Bard filters and he  
11:36:39 5 stopped using them because of reports of death that he was  
6 reading about.

7 THE COURT: What's your response?

8 MR. NORTH: Your Honor, all I asked him was whether  
9 he continued to do those ten filters after he knew about the  
11:36:54 10 fracture in the study and the migration in the study. I did  
11 not get into depth -- I didn't even ask him why he ultimately  
12 discontinued use of Bard filters.

13 THE COURT: Let me ask a different question,  
14 Mr. O'Connor.

11:37:05 15 During the break I went back to the Booker trial  
16 transcript to look at what Dr. Asch said on this. And at  
17 Docket 10 -- 10493, which is the Day 2 afternoon transcript  
18 from Booker, you asked him about this issue. The way you  
19 phrased it, there was a longer question, but at the end it  
11:37:26 20 was, "Did you learn things about the clinical experiences of  
21 your colleagues with the Recovery filters?"

22 Objection, hearsay.

23 I sustained the hearsay objection.

24 So that raised in my mind the question how do you  
11:37:40 25 intend to get in evidence that he heard from others that there



CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

1 were death problems?

2 MR. O'CONNOR: Because he was a member of the medical  
3 community. He reads the literature. He saw the reports.

4 THE COURT: That's all hearsay, isn't it?

11:37:55 5 MR. O'CONNOR: No, not in terms of what it's being  
6 used for. It's being used to show why he stopped. I'm not  
7 using it to prove the truth of the matter asserted.

8 To rehabilitate him, I think he has a right to say  
9 what he learned and what he knew and why he stopped.

11:38:15 10 THE COURT: Tell me what question you intend to ask.

11 MR. O'CONNOR: "Dr. Asch, did you stop using the  
12 filters? Why?"

13 THE COURT: What do you think he's going to say?

14 MR. O'CONNOR: Serious complications including death.  
11:38:29 15 That was well-known.

16 THE COURT: Mr. North.

17 MR. NORTH: First, I think it's hearsay.

18 Secondly, I do not think I opened the door in the  
19 least.

11:38:37 20 Made no issue about why he --

21 THE COURT: Well, you didn't, but you clearly made an  
22 issue about the fact he continued using the filter after the  
23 study was over. That's a big part of your argument to the  
24 jury is he kept using this filter.

11:38:52 25 MR. NORTH: After these two complications in his

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:38:53 1 study --

2 THE COURT: Right. Right.

3 MR. NORTH: -- that he tried to tell this jury made  
4 it necessary for a longer term study.

11:39:01 5 I think it's fair to say he continued to implant  
6 those. But I don't think for him to -- I do think there's a  
7 definite hearsay problem for him to come in and just say I  
8 quit using it because of what I read. But, secondly, I don't  
9 think that opens the door because I didn't make that point.

11:39:20 10 THE COURT: Well, I think you have opened the door to  
11 their asking why he -- whether he stopped and why he stopped.

12 If they introduce his statement that he heard about  
13 other complications, including death, and that's why he  
14 stopped, how is that being offered for the truth of the matter  
11:39:38 15 asserted?

16 MR. NORTH: It's being offered -- well, certainly he  
17 would not stop using it if he did not believe them to be true.  
18 Those statements to be true.

19 And why does he need to say "death" anyway? Because  
11:40:25 20 he can't prove those happened. He either knows they happened  
21 or it's just hearsay, he's just hearing it without knowing  
22 that they really did occur.

23 I think it's fair game for him to say he's heard of  
24 other complications.

11:40:53 25 THE COURT: I don't think he should be limited to

CROSS-EXAMINATION - MURRAY R. ASCH, M.D.

11:40:55 1 half an answer. If he's allowed to answer why he stopped, I  
2 think he should be allowed to answer.

3 So I'm going to allow you to ask the question. It is  
4 not being offered for the truth of the matter asserted.

11:41:04 5 If you want, I'll give an instruction that they're  
6 only to consider it for that purpose. But that does cast a  
7 bit of a light on that answer. I don't know if you want me to  
8 do that.

9 MR. NORTH: Right. I don't think so.

11:41:18 10 THE COURT: But I want to be clear. What I'm not  
11 ruling here is that the 403 ruling I've made repeatedly is  
12 being overturned. I still stand on that. I think it is  
13 relevant for this purpose of rehabilitating this witness, but  
14 I'm not opening the door to further inquiries --

11:41:32 15 MR. O'CONNOR: Understood.

16 THE COURT: -- you'll have to raise those as they  
17 come up.

18 MR. NORTH: And just so we don't come right up here,  
19 I will object on 403 grounds if he continues to go into detail  
11:41:41 20 about it because I think it's just the fact he's heard it  
21 that's relevant.

22 THE COURT: I understand the questions that are going  
23 to be asked and I think those are appropriate.

24 MR. O'CONNOR: Thank you.

11:41:51 25 THE COURT: Thank you all.

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:41:52 1 (Bench conference concludes.)

2 MR. O'CONNOR: May I proceed, Your Honor?

3 THE COURT: You may.

4 R E D I R E C T E X A M I N A T I O N

11:42:10 5 BY MR. O'CONNOR:

6 Q Dr. Asch, you were asked questions by defense about your  
7 use of Recovery filters after the study. Do you recall that?

8 A I do.

9 Q Did you stop using the Recovery filter?

11:42:23 10 A I continued to use the Recovery filter at my new hospital  
11 because I believe that it offered potential benefits to the  
12 patients. And although I was working at that time outside of  
13 the clinical study, I did clearly direct the ordering  
14 physician to do the follow-up that I had done in the study.

11:42:41 15 So number one, do routine abdominal radiographs, and, number  
16 two, to contact my team at the time when the IVC filter could  
17 and should be removed.

18 Q Different question. Did you eventually stop using the  
19 Recovery filter?

11:42:58 20 A Yes. I stopped using them when I had heard word on the  
21 street about the increase in the number of reported  
22 complications of the Recovery filter.

23 Q And what complications concerned you?

24 A The complications that I had experienced in my small  
11:43:12 25 trial: Fractures and migrations and death.

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:43:19 1 Q With respect to the Recovery filter?

2 A With respect to the Recovery filter, yes.

3 Q And did you ever go back to use the Recovery again?

4 A I have not.

11:43:36 5 Q Now, just in fairness, on your compensation, it's

6 actually -- in addition to what you talked about, there's also

7 compensation for your colleagues; is that correct?

8 A Yes.

9 Q And that was 20,000 as well?

11:43:50 10 A Right. Again, the compensation structure is identical

11 now as it has been always in my practice for anyone I'm

12 working for. Compensation for me, and if I need to replace

13 myself by hiring -- I hire someone, I need to pay someone to

14 do the work to allow me to be here today.

11:44:18 15 Q Now, Dr. Asch, you were asked about the complications in

16 your study and including the migration and the -- that you

17 talked about in Patient 9 and the fracture that you saw in

18 Patient 33. Do you recall that?

19 A Yes.

11:44:35 20 Q Now, how long were those patients involved in your study?

21 A I don't recall exactly. I believe Patient Number 9, I

22 believe his filter had been in a fairly short period of time.

23 I'm guessing a couple weeks. Patient 33 with the fracture, I

24 believe the filter was in approximately 75 days.

11:44:57 25 Q Did these complications occur in a relatively short period

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:45:00 1 of time?

2 A The complications occurred during those periods. So  
3 let's say a couple weeks and 75 days were the approximate  
4 length of time from filter insertion to the time of a  
11:45:09 5 complication.

6 Q At any time did you ever reach out to Bard -- you were  
7 asked questions before and one thing about the pregnant  
8 patient and your letter is you put in there that these  
9 patients need to be monitored. Do you recall that?

11:45:26 10 A Yes. Monitoring is essential.

11 Q After you had your concern that you learned about Bard  
12 filters, did you ever contact Bard?

13 A I did contact Bard. Now, at that time I was in a  
14 community practice. We didn't have the academic and research  
11:45:43 15 support to follow up on all of our patients, so I contacted  
16 Bard and I asked them for assistance in allowing me to  
17 identify and contact the patients that I had placed their  
18 device in so that I could bring them back, follow them up,  
19 evaluate them, and retrieve the filter, and they denied that  
11:46:04 20 request.

21 Q And did you contact them because of the concerns you  
22 learned about, about how -- the serious consequences of the  
23 Recovery filter?

24 A Yes. I heard -- after I had heard about the increased  
11:46:19 25 number of reports of adverse complications, I contacted Bard

REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:46:23 1 so I could get the filters out of my patients before there  
2 was a complication.

3 MR. O'CONNOR: Now, let me display Exhibit 567,  
4 please, Gay. Thank you.

11:46:39 5 BY MR. O'CONNOR:

6 Q Dr. Asch, did Bard ask you to write this letter?

7 A Yes, they did.

8 Q And did you have any idea who or where Bard intended to  
9 send this letter?

11:47:14 10 A Well, as I say, it was my understanding they were going  
11 to use this letter for the FDA in order to support the  
12 clinical trial that we talked about way back in my initial  
13 meeting with them in 1999 because they came to me initially  
14 because of the restriction in using a new device, new  
11:47:38 15 untested device, in American -- in the States, and so this  
16 letter, I thought, was meant to allow that study to occur.

17 MR. O'CONNOR: Let's publish this to the jury,  
18 please.

19 It's been admitted, Your Honor. May I publish?

11:47:54 20 THE COURT: Yes.

21 BY MR. O'CONNOR:

22 Q Dr. Asch, was this letter written before you stopped using  
23 the Recovery filter because of the serious complications you  
24 had learned about?

11:48:05 25 A Yes.

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:48:10 1 Q Did this letter concern -- was it limited to retrievable  
2 filters?

3 A This letter was -- again, it's a bit vague, but this  
4 letter was meant to support specifically the Recovery filter.

11:48:27 5 But the overall letter was to support the concept of a  
6 retrievable filter, but in this case the letter was specific  
7 in describing my use with the Recovery filter, again, so that  
8 a study could be done.

9 MR. O'CONNOR: Now, Gay, would you please show 5189.

11:48:55 10 BY MR. O'CONNOR:

11 Q Keep in mind, Doctor, the date of this letter is March 10,  
12 2003.

13 A Yes.

14 Q Thank you.

11:49:14 15 And you wrote the letter after the submission that --

16 MR. O'CONNOR: May I publish this to the jury,  
17 Your Honor? I believe it's admitted. 5189.

18 THE COURT: You may.

19 BY MR. O'CONNOR:

11:49:25 20 Q Dr. Asch, this is the submission to the FDA 510(k) that  
21 Bard made where they talked about using your study as  
22 substantial equivalence. Do you recall that testimony?

23 A Yes, I do.

24 Q Did you have any idea that Bard had used your study to  
11:49:39 25 support substantial equivalence for the Recovery's use as a



REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:49:42 1 permanent filter?

2 A I had no idea that they intended or did actually do that.

3 Q Would you ever have permitted any study you had done or  
4 any letter you had wrote to be used to support the permanent  
11:49:57 5 use of the Recovery filter?

6 A No. My study wasn't designed to test a permanent filter.  
7 I do not believe there is any scientific evidence to support  
8 this as a permanent safe filter.

9 Q Was it your understanding always that Bard intended to  
11:50:14 10 have a long-term clinical study?

11 A Yes. Yes, that was the constant discussion: We are  
12 looking forward to having a long-term study.

13 MR. O'CONNOR: Gay, would you please put up  
14 Exhibit 558. And go to the last page --

11:50:38 15 Excuse me, Your Honor.

16 BY MR. O'CONNOR:

17 Q 558, Dr. Asch, this is the report that you wrote following  
18 your short-term pilot study for Bard; correct?

19 A Yes.

11:50:52 20 Q And you were asked questions about this document by  
21 Mr. North. Do you recall that?

22 A Yes, I do.

23 MR. O'CONNOR: Would you go to the last page, Gay,  
24 please.

11:51:03 25 And, Gay, can you highlight the last sentence before

REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

1 the last paragraph. Do you see where I'm looking? "A large."

2 Can you narrow that a little bit.

3 Gay, highlight "A large", that sentence, please.

4 BY MR. O'CONNOR:

11:51:38 5 Q And, Dr. Asch, when you wrote your report, you reported --  
6 was it your intent to report to the medical community your  
7 findings in the pilot study?

8 A Yes.

9 Q Did it also include recommendations?

11:51:54 10 A Yes. The recommendation that you've highlighted here, a  
11 large multicenter study is warranted. And, again, I used  
12 words like "preliminary" and "suggest that" because you can't  
13 base --

14 Q Can you read what you wrote --

11:52:08 15 MR. O'CONNOR: Your Honor, may I display this to the  
16 jury?

17 THE COURT: Yes.

18 MR. NORTH: Your Honor, it's not in evidence.

19 THE COURTROOM DEPUTY: It's not in evidence.

11:52:14 20 THE COURT: 558? I show it in evidence.

21 MR. O'CONNOR: This is Exhibit 558.

22 THE COURTROOM DEPUTY: He talked about it but never  
23 moved it.

24 THE COURT: I show it as being admitted. You do not?

11:52:27 25 THE COURTROOM DEPUTY: I do not. He never said

REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:52:29 1 admitted.

2 THE COURT: Okay. I guess it's not in evidence.

3 MR. O'CONNOR: And it is a publication, Your Honor.

4 I'm just wondering for purposes of his testimony if we could  
11:52:36 5 just show the one highlighted sentence.

6 THE COURT: Well, are you using it under 803(18)?

7 MR. O'CONNOR: Yes, sir.

8 THE COURT: Can't be displayed to the jury, then.

9 BY MR. O'CONNOR:

11:52:50 10 Q Doctor, would you please read into the record the  
11 highlighted statement you wrote.

12 A "A large multicenter scientific study is warranted to  
13 further substantiate the role and value of this retrievable  
14 filter."

11:53:04 15 Q And is that something you had always expected Bard would  
16 do, a large multicenter scientific study?

17 A I had been told repeatedly by Bard and it was my  
18 expectation that a large study would be done following this  
19 pilot study.

11:53:20 20 Q And was one ever done as far as you learned?

21 A I'm not aware that a long-term study has ever been done.

22 Q Now, you were also asked questions about the letter that  
23 you wrote to a publication.

24 MR. O'CONNOR: Gay, would you please display  
11:53:38 25 Exhibit 555.

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:53:40 1 BY MR. O'CONNOR:

2 Q And, Doctor, again, what was the purpose of this letter?

3 A The purpose of this letter was to inform the medical

4 community of a significant complication, in spite of my

11:54:09 5 words, significant complication that occurred in a pregnant

6 woman. And I wrote this specifically because the timing of

7 this event occurred after the manuscript for the first 32

8 patients had been in progress. So the initial manuscript

9 that we just looked at didn't describe the filter fracture.

11:54:26 10 So I thought it was of the utmost importance that the

11 community, particularly the obstetric community, was aware

12 there was a new filter out there in the works and that a

13 complication, a significant complication, occurred in a

14 pregnant woman.

11:54:42 15 MR. O'CONNOR: Gay, would you please go to the second

16 page.

17 And, Gay, please, the last sentence in the

18 second-to-last paragraph, would you highlight that. Last

19 sentence, Gay. "Routine."

11:54:58 20 BY MR. O'CONNOR:

21 Q And, Dr. Asch, when you wrote that letter, did you include

22 recommendations based upon the experience you had in your

23 study?

24 A Yes. We altered our study throughout to emphasize and

11:55:22 25 increase the monitoring of these patients to ensure we

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

1 identified an asymptomatic complication before it became  
2 symptomatic.

3 Q Would you read the highlighted section to the jury, which  
4 includes your recommendation, please.

5 A "Routine abdominal radiography is thus recommended for  
6 all filter patients in order to identify filter fracture and  
7 migration."

8 Q Now, do you recall Mr. North asking you about the Bard IFU  
9 and how it mentioned the fracture that you had discovered?

10 A Yes.

11 Q Did the Bard IFU ever include a recommendation or  
12 instruction or warning to doctors that they should regularly  
13 monitor their patients with radiographs?

14 A I'm not aware that they instructed doctors to monitor  
15 their patients.

16 Q Was that what you were recommending needed to be done?

17 A Yes.

18 Q Did Bard ever indicate to you it would follow that  
19 recommendation?

20 A No, they did not.

21 Q Is it fair to say, Dr. Asch, that in response to  
22 Mr. North's question, before you found out about the bad  
23 events, did you still feel there was a use for retrievable  
24 filters?

25 A Yes. Retrievable filters offer great benefit to

## REDIRECT EXAMINATION - MURRAY R. ASCH, M.D.

11:56:39 1 patients, but they need to be tested and safe.

2 Q And was it your feeling they also need to be monitored on  
3 a regular basis?

4 A And they need to be monitored. Absolutely.

11:56:49 5 Q Are you aware of Bard ever warning the medical community  
6 that if it was going to use the Recovery or retrievable  
7 filter, it should regularly monitor and have radiographic  
8 imaging done on its patients?

9 A I'm not aware of any Bard recommendation that states  
11:57:03 10 that.

11 Q Was that your recommendation to Bard?

12 A That was my recommendation, yes.

13 MR. O'CONNOR: Gay, go to the very last sentence.

14 BY MR. O'CONNOR:

11:57:12 15 Q And, again, Mr. North asked you about this writing,  
16 Dr. Asch. And, Dr. Asch, you did make recommendations in  
17 everything you wrote when you wrote your literature; correct?

18 A Yes.

19 Q Would you read to the jury that last sentence.

11:57:43 20 A The last sentence in this manuscript states, "Further  
21 research is required to evaluate the benefits and risks of  
22 this intervention."

23 Q And was that your recommendation to Bard?

24 A That was my recommendation to Bard.

11:57:56 25 Q And did you ever receive any indication from Bard that

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11:57:58 1 they followed your recommendation?

2 A They did not inform me they followed this recommendation.

3 Q As a matter of fact, did you learn the opposite?

4 A I learned that they distributed this for widespread use  
11:58:12 5 across North America and Europe.

6 Q And, Dr. Asch, as we talked about, the complications that  
7 you saw, first of all, when you first saw the complications in  
8 Patient 9, did that concern you?

9 A Yes, that concerned me.

11:58:48 10 Q And did it indicate to you that the Recovery filter was  
11 not resisting migration?

12 A Yes. That was a sign that the filter was not designed in  
13 a way to make it secure and stable in position.

14 Q And when you had indicated that it saved a life, what did  
11:59:04 15 you mean by that?

16 A Well, I meant that theoretically putting it all together,  
17 the filter had trapped a large thrombus which, in the absence  
18 of the filter, could have contributed to patient illness.  
19 The filter caught the clot and could have saved a life.  
11:59:26 20 Could have saved a life.

21 Q And when you talked to Bard, what did you tell Bard about  
22 your concerns about that complication?

23 A I told them I'm very concerned that we've only put nine  
24 filters in and here is a significant migration.

11:59:41 25 THE COURT: Mr. O'Connor, we reached the lunch hour.

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11:59:43 1 MR. O'CONNOR: I just have one more, if I may, and  
2 I'll be done.

3 THE COURT: One more question?

4 MR. O'CONNOR: Yes, sir.

11:59:47 5 THE COURT: All right.

6 BY MR. O'CONNOR:

7 Q And was your concern serious injury or death?

8 A Yes.

9 MR. NORTH: Objection, Your Honor. 403.

11:59:57 10 THE COURT: Overruled.

11 All right. Ladies and gentlemen, we're going to take  
12 a one-hour break. We will plan to resume at 1 o'clock.  
13 Please remember not to discuss the case, and we'll see you  
14 then.

12:00:34 15 (The jury exited the courtroom at 12:00.)

16 MR. O'CONNOR: Your Honor -- excuse me.

17 Those are all the questions I had for Dr. Asch.

18 THE COURT: All right. Counsel, as of the noon hour  
19 today, plaintiff has used three hours and 26 minutes. Defense  
12:01:57 20 has used one hour and 47 minutes.

21 We'll see you at 1 o'clock.

22 MS. HELM: Your Honor, does that include the  
23 allocation of the transcript that was played?

24 THE COURT: No.

12:02:09 25 MS. HELM: Did you give the whole thing to the



12:02:10 1 plaintiff?

2 THE COURT: I did.

3 MS. HELM: In fairness, 11 minutes of that belongs to  
4 the defendant.

12:02:18 5 THE COURT: Okay. So that means plaintiffs are at  
6 three hours and 15 minutes and defendant is at one hour and 58  
7 minutes.

8 MR. O'CONNOR: Didn't mean to interrupt you before,  
9 Your Honor. I just wanted to ask if Dr. Asch may be excused.

12:02:38 10 THE COURT: Yes.

11 MR. O'CONNOR: Thank you.

12 THE COURT: All right. See you at 1 o'clock.

13 (End of a.m. session transcript.)

14 \* \* \* \* \*

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 16th day of May, 2018.

s/ Patricia Lyons, RMR, CRR  
Official Court Reporter